(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 August 2009 (20.08.2009)

PCT

(10) International Publication Number
WO 2009/101145 A1

(51) International Patent Classification:
A61M 5/158 (2006.01) *A61M 5/142* (2006.01)

(21) International Application Number:
PCT/EP2009/051653

(22) International Filing Date:
12 February 2009 (12.02.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PA 2008 00203 13 February 2008 (13.02.2008) DK
61/028,262 13 February 2008 (13.02.2008) US
12/187,971 7 August 2008 (07.08.2008) US

(71) Applicant *(for all designated States except US)*: **UNOMEDICAL A/S** [DK/DK]; Birkerød Kongevej 2, DK-3460 Birkerød (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **HASTED, Søren, Bo** [DK/DK]; Rosenvængets Allé 27A, DK-2100 København Ø (DK). **HØRDUM, Elo, Lau** [DK/DK]; Stenhavevej 14E, DK-2970 Hørsholm (DK). **GYRN, Steffen** [DK/DK]; Brogade 12, 3., DK-4100 Ringsted (DK).

(74) Agent: **NILAUSEN, K.**; Zacco Denmark A/S, Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) **Title**: MOULDED CONNECTION BETWEEN CANNULA AND DELIVERY PART

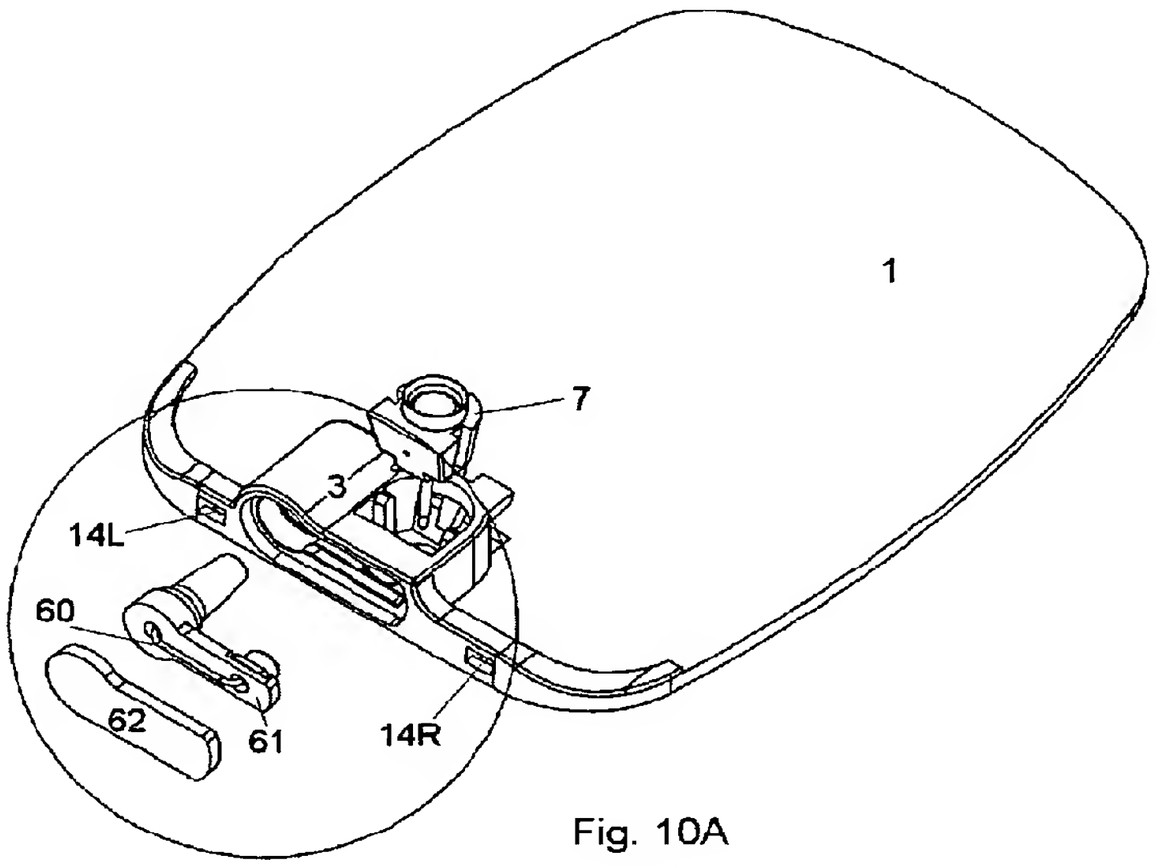


Fig. 10A

(57) **Abstract**: The invention relates to a fluid connection (60) having at least a first and a second opening (13, 12), i.e. an inlet and an outlet, where the first opening (13) forms a fluid connection to a medication supply (6) or the like and the second opening (12) forms a fluid connection to an opening in the body (24) of a separate cannula part (7) and an at least partly sub- or transcutaneous positioned cannula (22). The fluid connection is characterized in that is attached to a surface plate (1) and has the form of a tube (60) made of a rigid material. Further the invention relates to a base part comprising such a fluid connection.

WO 2009/101145 A1

Moulded connection between cannula and delivery part

The technical field

The invention relates to a device for continuous administration of a therapeutically working substance, such as insulin, comprising a base part to which an injection part and a delivery part can be fastened. A delivery part normally comprises a reservoir and e.g. a pump, and the injection part comprises a body with a through-going opening, and at least one cannula having a proximal end protruding from the lower side of the body. The invention comprises a fluid connection formed between a reservoir and a cannula part which fluid connection normally is attached unreleasably to the base plate and has the form of a tube made of a rigid material.

Prior art

WO 2007/071258 describes a medical device for delivering fluid comprising an injection part and a fluid delivery part where the fluid delivery part and the injection part can be separated and rejoined. The fluid delivery part comprises a reservoir, means for transport of liquid e.g. in form of a pump and a house in which the active units of the delivery part is placed. The injection part comprises: a base plate, a cannula part comprising a body with a through going opening provided with a cannula extending past the proximal side of the base plate and means for fixation of the base plate to the skin of the user e.g. in the form of a mounting pad. The delivery part and the injection part is assembled through a connector comprising a fluid path leading fluid from the reservoir to the through-going opening in the cannula part which fluid path comprises means for blocking access to the injection part when the connector is disconnected from the delivery part and/or the injection part. Fig. 20-24 in this document illustrates an embodiment where the connector is constructed of a molded body fastened unreleasably to a base plate and provided with an interior compartment to which access is protected by a septum. The septum can be penetrated by a connector needle belonging to the delivery part when the delivery part is fastened to the base plate. From the lower part of the interior compartment of the connector an opening 5a allows fluid to enter into a flexible tube and pass onto the cannula part 9. The flexible tube is connected to the first part of the injection part and

when the second part 1b of the injection part is positioned in the first part 1a a fluid path is created from the flexible tube 5 to the cannula 9.

The embodiments illustrated in this document are quite complex and not easy to manufacture.

The invention

The object of the invention is to provide a fluid connection between a reservoir and a cannula part which fluid connection is attached to a surface plate and has the form of a tube made of a rigid material. That the fluid connection is placed between the reservoir and the cannula part means that the fluid connection does not form part of either the reservoir or the cannula part e.g. the tube does not comprise the actual cannula which penetrates the patients skin. The tube can be releasably or unreleasably attached to the surface plate.

According to one embodiment the fluid connection is fastened to the surface plate by a holding part. The holding part 61 can either be made of one piece e.g. by moulding or combined from several pieces e.g. individual moulded pieces which after the individual manufacturing are assembled to the holding part 61.

According to one embodiment the tube is made of metal or plastic, e.g. the tube can comprise a hollow needle made e.g. of steel.

According to one embodiment the tube has a diameter or maximum cross-section smaller than 1 mm.

According to one embodiment the tube has at least one pointy end protruding from the holding part. That the end is “pointy” means that it has a sharp edge and can penetrate e.g. a protective membrane. This embodiment of the tube can be provided with a blunt end. That the end is “blunt” means that it does not have a sharp edge. Further according to this embodiment the pointy end of the tube can form a connector needle being the inlet to a connector part and when pushing a reservoir towards the inlet the connector needle

penetrates a membrane completely covering a first opening of the connector part.

According to one embodiment the tube consist of a single piece of material i.e. it is not assembled by several pieces but is e.g. moulded or made by extrusion.

According to one embodiment the tube is bend in an angle > 0 degrees in at least one position. According to this embodiment the tube can be bend in an angle > 0 degrees in at least two positions. Normally the angle will be larger than 45 degrees and according to one embodiment the angle is around 90 degrees. Further the angles of the two positions will normally be identical.

According to one embodiment the tube is stationary in relation to the surface plate after the tube has been attached to the surface plate.

According to one embodiment the contact surface of the surface plate has the same size as a credit card i.e. it covers a similar area and the length of the fluid path provided by the connection is max. 3 cm.

Embodiments of the invention will now be described with reference to the figures in which:

Figure 1 shows a first embodiment of a base part seen from above where a delivery part is connected through a membrane at a first opening and a cannula unit can be connected at a second opening.

Figure 2A shows the embodiment of fig. 1 joined with a delivery part and an inserter.

Figure 2B shows the same embodiment as fig. 2A seen from the end where the inserter is positioned.

Figure 3 shows the embodiment of fig. 1 joined with a delivery part and the cannula part in a pre-inserted position.

Figure 4 shows the embodiment of figure 3 seen from the end where the connection part is placed.

Figure 5A shows an embodiment of the base part provided with a surface plate which plate provides an outer cover for the connection part.

Figure 5B shows the same embodiment as fig. 5A of the base part where the outer cover has been removed.

Figure 6 shows an embodiment of the base part where the outer cover has been removed and the membrane covering the entrance from the reservoir also has been removed.

Figure 7 shows a second embodiment of the invention where the base part is provided with two longitudinal guiding means.

Figure 8 shows a first embodiment of a cannula part.

Figure 9A and 9B show a second embodiment of a cannula.

Figure 10A, B and C show one embodiment of a connection part according to the invention including the internal parts. Figure 10D shows a second embodiment of the internal parts of a connection part according to the invention.

Figure 11A-E shows several embodiments of sealings in the form of a bubble shaped membranes.

Figure 12A and 12B show a second embodiment of the internal parts of a fluid connection according to the invention.

Figure 13A and 13B show a third embodiment of the internal parts of a fluid connection according to the invention.

Figure 14 shows a fourth embodiment of the internal parts of a fluid connection according to the invention.

The figs. 1-6 show a first embodiment of a base part according to the invention. This embodiment comprises a surface plate 1 attached to a contact surface. The surface plate 1 is in this embodiment constructed of a

molded plastic material and the contact surface is the proximal side of a mounting pad 2 which mounting pad 2 is unreleasably fastened to the surface plate 1 during manufacturing of the device.

A connector part 3 is attached to or integrated with the surface plate 1. According to one embodiment the surface plate 1 and at least an outer cover of the connector part 3 is simply molded in one piece during manufacturing of the device. The connector part 3 forms a fluid path between e.g. a reservoir of medication or a reservoir for liquid collected from the patient and a cannula part 7. Therefore the connector part 3 is provided with at least two openings, one opening at each end of the fluid path (see fig. 5 and 6) where the first opening 13 is an inlet or outlet opening receiving or delivering fluid to a reservoir 6 and the second opening 12 is an inlet or outlet opening receiving or delivering fluid to a cannula part 7. The connection part 3 might be provided with extra openings e.g. for injection of a second medication or nutrient or for letting the fluid in the fluid path get in contact with a sensor. Fig. 1 shows the reservoir 6 attached to the connection part 3 at the first opening 13 of the connection part 3. In the following the first opening 13 will be referred to as “inlet” and the second opening 12 will be referred to as “outlet” although the direction of the flow through the fluid path is not significant for the invention.

The connection part 3 is further provided with a cannula opening 12A which accurately fits around a cannula part 7 when the cannula part 7 is mounted in the connection part 3 i.e. the cannula opening 12A has the same shape or profile as the cannula part 7 and is just big enough to let the cannula part 7 pass through and then fit into the opening. In fig. 1 the cannula part 7 is shown in a position where the cannula part 7 is not fully inserted, normally the cannula part 7 would at this stage of insertion still be placed inside an inserter and it would not be visible. When the cannula part 7 is fully inserted, the upper surface i.e. the distal surface of the cannula part 7 is normally at level with or at a lower level than the outer surface of the connection part 3 around the cannula opening 12A.

When the cannula part 7 has been fully inserted into the connection part 3, an opening 20 in a side surface of the body 24 of the cannula part 7 corresponds to the opening 12 of the fluid path of the connection part 3 and fluid can flow from one part to the other. The opening 20 in the body 24 of the cannula part 7 might in the following be referred to as an "inlet" although the direction of the flow is not significant to the invention.

Fig. 2A and 2B show a device which is ready to be placed on a patient's skin. Fig. 2A shows a side view of the inserter and fig. 2B shows a view from the inserter-end of the device. The device comprises a base part according to the invention which base part comprises a surface plate 1 positioned unreleasably on a mounting pad 2 with an adhesive proximal surface. Releasably connected to the base part is a delivery part 8 and an inserter 10 having an actuator handle 11. The actuator handle 11 is in a pre-insertion position.

The delivery part 8 of this embodiment is joined to the base part by pushing the delivery part 8 down toward the guiding means 4 which in this case is a longitudinal raised platform having a metal lining 5 fastened to the top surface. The delivery part 8 is provided with a corresponding groove corresponding to the size of the metal lining 5 on the raised platform 4, in such a way that the corresponding groove of the delivery part 8 can slide along the metal lining 5 on the raised platform 4 of the base part in the longitudinal direction. When the delivery part 8 arrives at its working position, two release handles 9 engage respectively with two protruding parts 15 protruding from the upper surface of the surface plate 1. When the delivery part 8 is in its working position it is locked in any horizontal direction by the release handles 9 and the raised platform 4 with the metal lining 5 placed in the corresponding groove of the delivery part 8. These locking mechanisms make it possible to fasten and release the delivery device from the base part as often as needed i.e. a single-use base part can be combined with a multi-use delivery part.

The inserter 10 holds the cannula part 7 before insertion and the insertion is initiated by pushing a handle 11. Fig. 2B shows the direction the handle 11

has to be pushed in order to initiate insertion of the cannula part 7. After insertion a not shown insertion needle can be retracted to the inside of the inserter 10 and the inserter 10 can be removed from the base part, leaving an inserted cannula 22 fastened to the surface plate 1 of the base part. If the cannula 22 of the cannula part 7 is a hard self penetrating cannula there will be no separate insertion needle and therefore no need to retract the insertion needle.

Fig. 3 shows a side view of the same embodiment as shown in fig. 2A and 2B but in fig. 3 the inserter has been removed. The cannula part 7 has the same position as it would have inside the inserter 10 before insertion.

Fig. 4 shows the same embodiment as fig. 3 but in fig. 4 the assembly is shown from the end of the connection part 3 and the cannula part 7 has been removed. From this end it is possible to see the fastening means 14L and 14R of the base part which correspond to parts on the inserter 10. These fastening means comprise two openings 14L and 14R in the connection part 3 which correspond to two not shown protruding parts on the inserter 10. When the fastening means 14 on the base part is engaged with the corresponding fastening means on the inserter 10, the inserter 10 is prevented from moving in relation to the base part, at least in the direction perpendicular or a direction having a component perpendicular to the surface plate 1.

The figs. 5A and 5B show the connection part 3 of the base part. In fig. 5A the connection part 3 is shown with an outer cover provided by the moulded surface plate 1 and in fig. 5B the connection part 3 is shown without the outer cover i.e. only a mounting pad is shown. The outer cover shown in this embodiment is not a separate unit but is attached unreleasably to or simply made as a part of the surface plate 1 e.g. during a moulding process. The outer cover is provided with the cannula opening 12A for the cannula part 7 and an access opening 13 for the reservoir 6 thereby allowing access to the fluid path of the connection part 3 by the reservoir and the cannula part 7. The cannula opening 12A allows the cannula part 7 to be inserted sub- or transcutaneous into the patient within the circumference of the surface plate

1 and the contact surface 2 of the base part which in this embodiment is provided by a mounting pad is also provided with an opening 12B which allows for the cannula to be inserted (see fig. 5B). This opening 12B is not necessary if the contact surface 2 is constructed of such a material and thickness that it can be penetrated by at least the cannula 22 of the cannula part 7.

In order to secure a fluid tight connection between the outlet opening 12 in the connection part 3 and the cannula part 7 the outlet opening 12 of the connection part 3 is provided with an elastic sealing 18 around the outlet opening 12. When the cannula part 7 is inserted it will be press fitted into the cannula opening 12A and the elastic sealing 18 will provide a completely fluid tight gasket around the corresponding openings 12 and 20. In order to improve the press-fitting and thereby the fluid tight connection between the cannula part 7 and the outlet of the fluid path, the cannula opening 12A can be provided with a decreasing cross-section in a plane parallel to the cannula 22 when inserted and perpendicular to the surface where the outlet of the fluid path is positioned. The cannula part 7 will have a corresponding decreasing cross-section.

In order to secure a fluid tight connection between the inlet opening 13 in the connection part 3 and the reservoir 6, a bubble shaped membrane 17 has been positioned in the first opening 13. The membrane 17 completely covers the inlet opening 13 (which according to this embodiment could be understood as being the open end of a connector needle 19) and prevents contamination of the connection part 3. When the reservoir 6 is pressed towards the connection part 3, the connector needle 19 will penetrate the membrane 17 and provide a completely fluid tight transferral of fluid between the connection part 3 and the reservoir 6.

That the membrane 17 is bubble shaped means that it is attached around the opening in a way where it surrounds the opening – often it is placed at the edge of the opening it protects – and the membrane 17 protrudes from the planed formed by the edge of the opening and forms a dome in a distance

from the edge. The height or length of the dome can correspond to the length of a connector needle 19.

In fig. 6 the connector needle 19 is shown as being a part of the connection part 3 i.e. it is attached to the connection part 3 but the connector needle 19 might just as well be a part of the reservoir 6.

According to one embodiment the connection part 3 is provided with both a connector needle 19 and a bubble shaped self closing membrane 17 and the reservoir 6 is also provided with a bubble shaped self closing membrane. As both parts are provided with self closing membranes it will be possible to separate the two units from each other and rejoin them at a later time without the connection part 3 and thereby the patient being contaminated.

Fig. 7 shows a second embodiment of the base part. This embodiment is provided with two guiding means 4 in the form of two right angled profiles shaped as: ┐ ┌, and protruding from the surface plate 1 of the base part. The guiding means 4 correspond to means on a delivery part or a cover which is to be fastened to the base part. Such corresponding means can e.g. be formed as one or more hooks having a profile in the form of ┘ and └.

The fluid path of the connection part 3 is very short compared to the embodiment shown in fig. 1-6 and the inlet of the connection part 3 is placed in a centre position in relation to the guiding means 4 but the inserted cannula part 7 has the same profile as the cannula part 7 fitted to the embodiment of fig. 1-6.

Fig. 8 shows an enlargement of the cannula part 7 shown in fig. 1. This embodiment comprises a body 24 provided a cannula 22 and with a protruding front 25 having a flat surface. The surface of the cannula part 7 having an opening need not be flat; it can actually have any desired shape as long as it is possible to create a corresponding surface on the connection part 3 facing the cannula part 7. In one embodiment the front 25 is inclined in such a way that the cross-section at the upper i.e. distal end is larger than the cross-section at the proximal end, i.e. the enc closest to the patient after

insertion, of the front. The front 25 is provided with an opening 20 through which liquid can exit or enter the cannula part 7. The body 24 is further provided with a top opening 21 which opening can be covered with a self closing membrane. The opening 21 need some kind of entrance protection as it is facing an outer surface which is in contact with the surroundings. The top opening 21 is primarily used when inserting the cannula part 7 if the cannula 22 is a soft cannula. That the cannula 22 is soft means that is made of a relatively soft material which can not penetrate the patients skin, in this case it is necessary to use a pointy insertion needle of a relatively hard material when inserting the cannula and this pointy needle can be inserted through the top opening 21, pass through an inner hollow in the body 24 of the cannula part and further pass through the full length of the cannula 22 in such a way that the pointy end of the insertion needle stick out of the open end of the hollow cannula 22. After insertion i.e. after the cannula 22 has been placed sub- or transcutaneous in the patient, then the insertion needle is retracted and the cannula 22 is left inside the patient.

Fig. 9 shows an enlargement of a second embodiment a cannula part 7. This embodiment also comprises a body 24 provided with a cannula 22 and with a protruding front 25 having a flat surface provided with an opening 20 but according to this embodiment the protruding front 25 is inclined in such a way that the pressure between the opening 20 and the sealing 18 around the second opening 12 of the connection part 3 is increased. The inclination of the front 25 is defined by the angle d between the centre line c of the cannula 22 and a line parallel to the surface around the opening 20. The angle d will be larger than 0°and smaller than 90°, normally $d \in]0°, 30°]$ depending on the diameter or the protrusion of the sealing 18 or [60°, 90°[. The distance d_1 between at the distal end of the surface of the protruding part 25, i.e. the end of the cannula part 7 which is furthest away from the patient after insertion, and the centre c of the cannula part 7 is larger than the distance d_2 between the surface of the protruding part 25 at the proximal end, i.e. the end closest to the patient after insertion, and the centre c of the cannula part 7. Normally the distance d_2 will be so small that the proximal end of the protruding front 25 does not touch the sealing 18 of the connection part 3 during insertion.

In one embodiment (not shown) the angle d is close to 90° i.e. d = 90°, such an embodiment would in a drawing corresponding to fig. 9A and 9B appear to have an upward opening 12 of the connection part 3 fitting to a downward opening 20 of the cannula part 7. This means that the force pushing the cannula part 7 toward the sealing 18 will be close to perpendicular to the contact surface of the sealing 18 and this will prevent that the sealing is distorted during insertion of the cannula part 7 by the cannula part 7 sliding along the sealing 18.

In another embodiment (shown in fig. 8) d = 0° as the protruding front 25 and the centre line c are parallel. According to this embodiment the cannula part 7 will be in sliding contact with the protruding sealing 18 which can cause the sealing to be distorted.

As according to the embodiment of fig. 8 the protruding front 25 of the cannula part 7 need not be flat; it can actually have any desired shape as long as it is possible to create a corresponding surface on the connection part 3 facing the cannula part 7. Also the opening 20 of the protruding front 25 can be an inlet or an outlet depending on the purpose of the cannula part 7. In fig. 9 which is a cut-through view it is shown how the top opening 21 of the body 24 is covered with a self closing membrane 21A. As according to the embodiment of fig. 8 the top opening 21 is primarily used when inserting the cannula part 7 if the cannula 22 is a soft cannula but the top opening 21 can also be used to inject medication or nutrients other than the primary medication which could be e.g. insulin which the patient receive via the opening 20.

This embodiment of the cannula part 7 is also provided with fastening means 23 and in this embodiment the fastening means 23 has the form of a protruding part 23 on the cannula part 7 which corresponds to a flexible part 23A on the stationary base part. The flexible part 23A can be pushed outward as indicated with an arrow at fig. 11 when the protruding part 23 on the cannula part 7 passes during insertion of the cannula part 7. After insertion the upward surface of the protruding part 23 of the cannula part 7 will be locked by the downward surface of the flexible part 23A of the base

part and it will not be possible to detach the cannula part 7 from the base part.

Fig. 10A-C show one embodiment of a connection part 3. Fig. 10A show the embodiment of the connection part 3 in an exploded view where the internal holding parts 61 for a tube 60 providing a fluid path is shown. Fig. 10B shows a cut through the internal holding part 61 according to which it is possible to the position of the tube 60. Fig. 10C shows an enlargement of the encircled part of fig. 10A.

According to the present embodiment the connection part 3 and the surface plate 1 is molded in one piece of a plastic material, the connection part is provided with several openings, one opening 12A is prepared for fitting in the cannula part 7 and another opening is prepared for fitting in the internal parts of the connection part 3. The internal parts of the connection part 3 according to this embodiment comprises one tube which at two positions are bend in 90° i.e. both the inlet and the outlet end of the tube 60 points in the same direction perpendicular to the connecting part of the tube 60 where the connecting part of the tube 60 forms the fluid path between the two bending parts.

At one end the tube 60 is protected by a bubble shaped membrane 17 and at the other end the tube 60 is open and unprotected, but the open tube end is surrounded by a sealing 18 which is attached unreleasably to a holding part 61. When the internal parts has been placed in the corresponding opening in the connection part 3 a cover 62 accurately fitting in the opening is placed in level with the surface of the connection part 3 in such a way that the user experience a smooth surface which cannot be tampered with.

Fig. 10B shows an enlargement of the internal parts of the connection part 3. The holding parts 61 comprise a single molded part which is providing a stable embedment of the tube 60. The open blunt end of the tube 60 opens into a space surrounded by the sealing 18. The closed pointy end of the tube 60 is completely surrounded by a soft membrane. The end of the tube 60 which constitutes the connector needle 19 is in this embodiment not actually

in touch with the surrounding membrane 17. The connector needle 19 is surrounded by air, and the internal space surrounding the connector needle 19 has a cylindrical or conical shape i.e. a circular cross-section. The walls of the membrane 17 will deform by bending inwards or outwards when the length of the membrane is reduced as a result of the applied pressure.

Fig. 10C shows an enlargement of the enclosed field marked in fig. 10A.

Fig. 10D shows an enlargement of the internal parts of a second embodiment of a connection part 3. Also according to this embodiment the holding parts 61 comprise a single molded part which provides a stable embedment of the tube 60 but in this embodiment the holding part 61 is circular or cylindrical and a non-rigid sealing part 18 is attached to the blunt end of the tube 60 i.e. the open blunt end of the tube 60 opens into a space surrounded by sealing material. The closed end of the tube 60 which is as in the embodiment of fig. 10B pointy is completely surrounded by a soft membrane 17 and the holding parts 61 provide the internal parts with enough stability to push the assembled internal parts into position in an adapted opening in the connection part 3. For all embodiments “Completely surrounded” means that there is no free access to the surroundings, and “soft membrane” means that the membrane can be penetrated by a needle, especially the connector needle 19 which is provided by the end of the tube 60 and which is embedded inside the soft membrane 17.

Nor according to this embodiment is he connector needle 19 actually in touch with the surrounding membrane 17. The connector needle 19 is surrounded by air, and the internal space surrounding the connector needle 19 has a cylindrical or conical shape i.e. a circular cross-section. The walls of the membrane 17 will deform by bending inwards or outwards when the length of the membrane is reduced as a result of the applied pressure.

Fig. 11A shows an enlargement of an embodiment of a bubble membrane 7. This bubble membrane 17 completely surrounds the part of the connector needle 19 which protrudes from the surface of the holding part 61 in which the connector needle 19 is embedded. The connector needle 19 does not

touch the bubble membrane 17 when no pressure is put on the membrane 17 i.e. the connector needle 19 is completely surrounded by air which makes it possible to gas sterilize the connector needle 19; this is the state in which the membrane is shown in the figure. The tip of the connector needle is surrounded of membrane parts with quite thick walls, while the part of the membrane closest to the holding part has walls of approximately half this thickness, this has the result that when pressure is put on the membrane the thick walled part does not change shape, in stead the part of the membrane having reduced wall thickness i.e. the part closest to the holding part will give in and be pressed toward the holding part 61.

Fig. 11B shows another embodiment of a bubble shaped membrane 17. According to this embodiment the reservoir 6 which is provided with an entrance protecting membrane 6A is pushed toward the membrane covered connector needle 19. The bubble membrane 17 is made of a flexible material which makes it possible for the membrane to be deformed to such an extent that the connector needle 19 can penetrate the protecting membrane 6A and assure access to the fluid reservoir 6.

Fig. 11C shows yet another embodiment of a membrane 17 protecting the opening to the connection part 3. This membrane 17 is not bubble shaped but it provides a wall in a space surrounding the connector needle 19. The wall is pliant i.e. it will move back when the reservoir is pressed against it. The membrane wall 17 is kept in position by one or more springs i.e. the membrane 17 is able to return to the original position when the pressure from the reservoir 6 which keeps it in place is released. The opening in which the membrane slides back and forth closely fits the connecting part of the reservoir 6.

Fig. 11D shows another embodiment of a reservoir 6 where a bubble membrane 6A is mounted at the outlet of the reservoir 6 which outlet is connected to the fluid path of the connection path 3. The not shown end of the fluid path connecting to the reservoir 6 is provided with a membrane protecting the entrance of the fluid path during periods where the fluid path is not connected to the reservoir 6. According to this embodiment the fluid path

need not be provided with a connector needle 19 as the connector needle 19 according to this embodiment is part of the reservoir 6.

Fig. 11E shows yet another embodiment of a bubble membrane 17 and how the reservoir is pressed against the connector needle 19 in order to provide a fluid path for the medication contained in the reservoir 6. The bubble membrane 17 is flexible and is able to be reduced in size in such a way that it allows the entrance of the reservoir 6 to be pressed into the opening in the connection part 3 which surrounds the membrane 17 and the connector needle 19 i.e. the length of the membrane 17 can be reduced without the diameter of the membrane 17 need to be extended. According to the shown embodiment the material of the membrane will be folded inwards.

Fig. 12A and 12B show an alternative embodiment which provides a fluid tight connection when transferring liquid from the reservoir 6 to the cannula part 7. Both in fig. 12A and 12B the internal parts of the connection part 3 are presented in exploded form.

The internal parts of the connection part 3 according to this embodiment comprises a holding part 61 for a tube 60, fastening means 18a for a sealing around the second opening 12, fastening means 61a for the soft bubble membrane 17 separated from the holding part 61 and provided with a sealing opposite of the fastening means 61a, a connector needle 19 and a soft bubble membrane 17.

The tube 60 can be constituted either by a straight or by a bended piece of pipe-shaped rigid material such as steel or a hard plastic material, and the tube 60 is held by a holding part 61 which holding part 61 according to this embodiment also provides for a cover surface which cover surface is constituted by the outer side of the holding part 61 shown in fig. 12A. If the tube 60 is a straight piece of material the second end of the tube 60 which is the end connected to the cannula part 7, opens into a room formed in the holding part 61 and having an inlet/outlet to the cannula part 7 through a small opening 18c in the fastening means for the sealing 18a. If the tube 60 is a bended piece of material the second end of the tube 60 is bended in a 90

degree angle through the small opening 18c which is formed in the fastening means 18a. The fastening means 18a provide the means for fastening of the sealing 18 to the holding part 61. The fastening means 18a are provided with a large opening 18b which opening provides a connecting room between the tube 60 and the connector needle 19 when the holding part 61, the fastening means 18a and a separate sealing part 61b are pressed together. The connecting room provides a fluid connection between the connector needle 19 and the tube 60 as the room can fill with fluid entering from the connector needle 19 where after fluid can exit the connecting room by exciting through the tube 60. The side of the fastening means 61a for the membrane which is turned toward the fastening means 18a for the sealing can be provided with a sealing in order to keep the connecting room fluid tight.

Fig. 13A and 13B show another embodiment of the connection part compared to the connection part shown in fig. 10A-C, which connection part 3 comprises the same units. Fig. 13B shows where internal parts of the connection part 3 are positioned in relation to the outer parts of the connection part 3. Fig. 13A shows an exploded view of the internal parts of the connection part 3 which internal parts are encircled in fig. 13B.

Like in fig. 10A-C the holding parts 61 comprise a single molded part. The holding part 61provides a stable embedment of the tube 60, the holding part 61 is normally molded in one part but it might be formed by joining two or more smaller parts. Such smaller parts could be joined by welding or gluing. As the holding part 61 is rather small, normally less than 2 cm in length, it can be difficult to join the smaller parts.

The tube 60 has two open ends, i.e. liquid can pass in or out, and when the tube 60 is mounted in the holding parts 61, the first open end opens into a space surrounded by the closed soft membrane 17 and the second open end opens into a space surrounded by the sealing 18.

The first end of the tube 60 is pointed i.e. sharp and can provide a connection to the reservoir 6 as this first end of the tube 60 can penetrate both the closed soft membrane 17 surrounding the open end of the tube 60 and a

membrane 6A protecting the inlet to the reservoir 6. Like in the embodiment shown in fig. 10A-C this end of the tube 60 is completely surrounded by a soft membrane 17 where "completely surrounded" means that there is no free access from the first open end of the tube 60 to the surroundings, "soft membrane" means that the membrane can be penetrated by a needle, especially the connector needle 19 provided by the end of the tube 60. The end of the tube 60 which constitutes the connector needle 19 is in this embodiment not in touch with the surrounding membrane 17 when the soft membrane 17 is not influenced by impacts from the surroundings. The soft membrane 17 is according to this embodiment fastened to the holding part 61 by pressing the relatively soft and compliant membrane material against the holding part 61, the edge of the membrane 17 being closest to the holding part 61 can expand in diameter and slide over a mushroom shaped fastening part 61a which is an unreleasable part of the holding parts 61. When the soft membrane 17 is in its final position, the extended diameter of the membrane 17 can return to a smaller size and this reduction of the diameter will keep the membrane 17 in place around the fastening part 61a. The fastening of the membrane 17 is enhanced if the membrane 17 is provided with one or more inward protruding parts which will rest against the part of the fastening means 61a being closest to the holding parts 61 and having the smallest diameter after mounting of the membrane 17.

The second open end of the tube 60 is blunt and opens into a closed ring of sealing 18 i.e. the sealing has the form of a short pipe and do not stop the flow of liquid in or out of the tube 60. The sealing 18 is fastened to the holding parts 61 by fastening means 18a, the fastening means 18a makes it easier to e.g. weld or glue the sealing 18 unreleasably to the holding part 61.

The tube 60 is formed in one piece; normally it will be made of steel or a hard plastic material. If the tube is formed with a pointed end which is to penetrate the soft membrane 17 during use, it should at least be made of a material which is hard enough to penetrate the soft membrane 17 and e.g. the membrane 6A covering the inlet to the reservoir 6. It is possible to construct the tube 60 with two blunt ends, according to such an embodiment the reservoir

6 could be provided with a connector needle 19 which could penetrate the soft membrane 17 when transferring liquid to the cannula part 7.

According to the embodiment of fig. 13A-B, the tube 60 is bended at two positions. This is suitable according to this embodiment as the reservoir 6 and the cannula part 7 are mounted on the same side relative to the holding parts 61. The angles of both the bends are 90 degrees, if the tube 60 is to be positioned in a one piece holding parts 61 by pushing, then the two legs provided by these two bends should have the same angle in relation to the connecting tube piece between the two bends but the angles need not be 90 degrees. If the reservoir 6 and the cannula part 7 are positioned different in relation to each other the tube 60 might be bend only once e.g. in the situation where the cannula part 7 is positioned close to the edge of the surface plate 1 and has the front provided with the opening 20 turned toward the first and only bending of the tube 60.

According to one embodiment the tube 60 comprises a hollow needle e.g. made of steel. Such a needle can easily be manufactured at an automated process at a low price. Also such a needle can easily be bending in one or more positions in order to satisfy any need there would be for positioning of the needle between the reservoir 6 and the cannula part 7. Whether the needle is provided with blunt or pointed ends can depend on the parts corresponding at the ends of the needle but normally the needle will be provided with at least one pointed or sharp end which is able to penetrate a protective membrane.

Also if the connection part 3 is placed on a middle or central part of the surface plate 1, then the reservoir 6 could be placed at one side of the connection part 3 at the first end of the tube 60 and the cannula part 7 could be placed at the opposite side of the connection part 3 at the second end of the tube 60 and then the tube 60 could be straight without any bending.

According to the present invention the tube 60 is stationary relative to the surface plate 1 after the tube 60 has been positioned in the holding part 61 and mounted on the surface plate 1. That the tube 60 is stationary means

that it does not pivot or in any way move back or forth in relation to the surface plate 1, the tube 60 simply serves as a path for transporting liquid.

Figure 14 discloses a fourth embodiment of a fluid connection according to the invention. This embodiment illustrates a method to uptake tolerances with regards to tolerances on the bended tube 60 which is also referred to as a needle. A bended tube 60 having two bends of each 90° as shown in fig. 14 will have a length tolerance between the bends, the tube 60 according to this embodiment is constructed of a connector needle 19, a blunt end needle 60b at the opposite end of the tube 60 and a connector piece 60a between the two 90° bends. The length of respectively the connector needle 19 and the blunt end needle 60b are supposed to fit into two through holes in the holding part 61. The two through holes have to have a tolerance allowing both the connector needle 19 and the blunt end needle 60b to enter the desired position in the holding parts 61. One way to ensure that the two ends will fit into the holes is to make the through holes large enough to obtain the tolerance of both the minimum and maximum material conditions. This though is not a good idea for several reasons: 1. if the tube 60 is to be glued into the connection part 3, the glue will run through the holes in too large amounts, 2) not enough control of the needle tip positions are obtained.

In order to get a tight control over the needle tip position interference fit on the connector needle 19 would be beneficial; interference fit would prevent the glue from running through the through hole and would make it possible to place the needle tip with great precision. Then all of the tolerance would have to be taken into account in the end of the blunt needle 60b and this can be done e.g. by making an elongated through hole for the blunt end needle which through hole in the dimension perpendicular to the length of the connector piece 60a is just larger than the outer diameter of the tube 60, and in the dimension parallel to the length of the connection piece 60a is long enough to take up all the tolerance i.e. this dimension could be e.g. 1½-2 times the diameter of the tube 60.

This however does not solve the problem with regard to the glue running through the hole at the blunt needle end, although having one hole sealed mechanically makes it easier to control the flow of glue out of the other.

The inner parts shown in fig. 14 show a solution to the problem of providing interference fit and tolerance at the same time. In this embodiment a first end of the tube 60 i.e. the end providing the pointy connection needle 19 is fitted closely into a through hole in the holding part 61. The second end of the tube 60 i.e. the blunt end, is fitted into a through hole with a tolerance gap surrounding the tube. The through hole providing the tolerance and surrounding the second end discharge into a space with an increased diameter / dimension, this means than when glue is pressed into the opening around the tube 60 from the open side of the holding part 61, the flow of glue will be slowed down when having passed the tolerance gap. Further, when the holding parts 61 are irradiated with e.g. UV light, the UV-light will cure any glue that comes through the tolerance gap.

Ref No	Name
1	Surface plate
2	Mounting pad
3	Connection part
4	Guiding means
5	Metal lining
6	Reservoir
6A	Membrane for reservoir
7	Cannula part
8	Delivery part
9	Release handles of delivery part
10	Inserter
11	Actuator handle for inserter
12	Outlet or Second opening
12A	Cannula opening
12B	Opening in surface plate for cannula part
13	Inlet or First opening
14	Fastening means for inserter
15	Protruding parts of base part
16	-
17	Bubble membrane
18	Sealing around outlet or second opening
18a	Fastening means for sealing
18b	Large opening in fastening means 18a
18c	Small opening in fastening means 18b
19	Connector needle
20	Opening into cannula part
21	Top opening in cannula part
21A	Self closing membrane
22	Cannula
23	Fastening means
24	Body of cannula part
25	Protruding front
60	Tube / needle
60a	Connector piece
60b	Blunt needle
61	Holding part for tube
61a	Fastening means for membrane
61b	Separate sealing part
62	Cover
63	Molded fluid path

Claims:

1. Fluid connection (60) having at least a first and a second opening (13, 12), i.e. an inlet and an outlet, where the first opening (13) forms a fluid connection to a medication supply (6) or the like and the second opening (12) forms a fluid connection to an opening in the body (24) of a separate cannula part (7) and an at least partly sub- or transcutaneous positioned cannula (22) **characterized in** that the fluid connection is attached to a surface plate (1) and has the form of a tube (60) made of a rigid material.

2. A fluid connection according to claim 1, **characterized in** that the fluid connection (60) is fastened to the surface plate (1) by a holding part (61).

3. A fluid connection according to claim 1 or 2, **characterized in** that the tube (60) is made of metal or plastic.

4. A fluid connection according to claim 3, **characterized in** that the tube (60) comprises a hollow needle made e.g. of steel.

5. A fluid connection according to any of the claims 1-4, **characterized in** that the tube (60) has a diameter or maximum cross-section ≤ 1 mm.

6. A fluid connection according to any of the claims 1-5, **characterized in** that the tube (60) has at least one pointy end (19) protruding from the holding part (61).

7. A fluid connection according to claim 6, **characterized in** that the tube (60) has a blunt end.

8. A fluid connection according to claim 6 or 7, **characterized in** that the pointy end of the tube (60) forms a connector needle (19) being the inlet to a connector part (3) and when pushing a reservoir (6) towards the inlet the connector needle (19) penetrates a membrane (17) completely covering a first opening (13) of the connector part (3).

9. A fluid connection according to any of the claims 1-8, **characterized in** that the tube (60) consists of a single piece.

10. A fluid connection according to claim 9, **characterized in** that the tube (60) is bend in an angle > 0 degrees in at least one position.

11. A fluid connection according to claim 10, **characterized in** that the tube (60) is bend in an angle > 0 degrees in at least two positions.

12. A fluid connection according to claim 11, **characterized in** that the angles of the two positions are identical.

13. A fluid connection according to any of the claims 1-12, **characterized in** that the tube (60) is stationary in relation to the surface plate (1) after the tube has been attached to the surface plate (1).

14. A base part which is connectable to a separate cannula part (7) having a body (24) provided with a cannula (22) and which can be positioned on a patients skin comprising

- a contact surface (2) for fastening the base part to the patient,
- fastening means (4) connecting medication supply (6) or the like to the base part,
- a connection part (3) being a part of the base part which connection part (3) comprises a fluid connection according to any of the claims 1-14 **characterized in** that the connection part (3) is rigid and each opening (13, 12) is either provided with a sealing (17, 18) or adapted to fit with a corresponding sealing of an adjacent part.

15. A base part according to claim 14, **characterized in** that the connection part (3) or at least an outer cover of the connection part (3) is moulded of a plastic material.

16. A base part according to claim 14 or 15, **characterized in** that at least one of the openings (12, 13) is combined with a sealing material (17, 18).

17. A base part according to claim 14, 15 or 16, **characterized in** that each opening (12, 13) is provided with means providing a fluid tight and non-contaminated transfer of fluid from reservoir to cannula part (7) once the separate cannula part (7) is inserted.

18. A base part according to claim 17, **characterized in** that the first opening (13) is provided with a septum (17) which can be penetrated by a rigid needle (19), which septum (17) recloses upon retraction of the rigid needle (19).

19. A base part according to any of the claims 14-18, **characterized in** that the first opening (13) is provided with a flexible bubble shaped membrane (17) which completely covers the first opening (13) which membrane (17) can be penetrated by a blunt or pointy needle.

20. A base part according to any of the claims 14-19, **characterized in** that a connector needle (19) forms the inlet to the connector part (3) and when pushing a medication supply part (6) or the like towards the inlet, the connector needle (19) penetrates the membrane (17) completely covering the first opening (13).

21. A base part according to any of the claims 14-20, **characterized in** that either the first (13), the second (12) or both openings are provided with a sealing (18) positioned at the edge of the opening i.e. the sealing allows unrestricted access to the fluid connection (60).

22. A base part according to claim 21, **characterized in** that the opening (12 and/or 13) is round and the sealing is an O-ring.

23. A base part according to any of the claims 14-22, **characterized in** that the sealing of the second opening (12) is provided either by fastening a sealing material round the edge of the second opening (12) or by fastening a sealing material round the edge of the opening into the cannula part (7).

24. A base part according to any of the claims 14-20, **characterized in** that the contact surface (2) of the base part has the same size as a credit card i.e.

it covers a similar area and the length of the fluid connection provided by the connection part (3) is max. 3 cm.

25. A base part according to any of the claims 14-24, **characterized in** that the inlet (13) to the connector part (3) is covered by a bubble shaped deformable membrane (17) which membrane (17) prevents the access of micro organisms to the connector part (3) when the delivery part is not joined to the connector part (3).

26. A base part according to claim 25, **characterized in** that the inlet (13) to the connector part (3) comprises a connector needle (19).

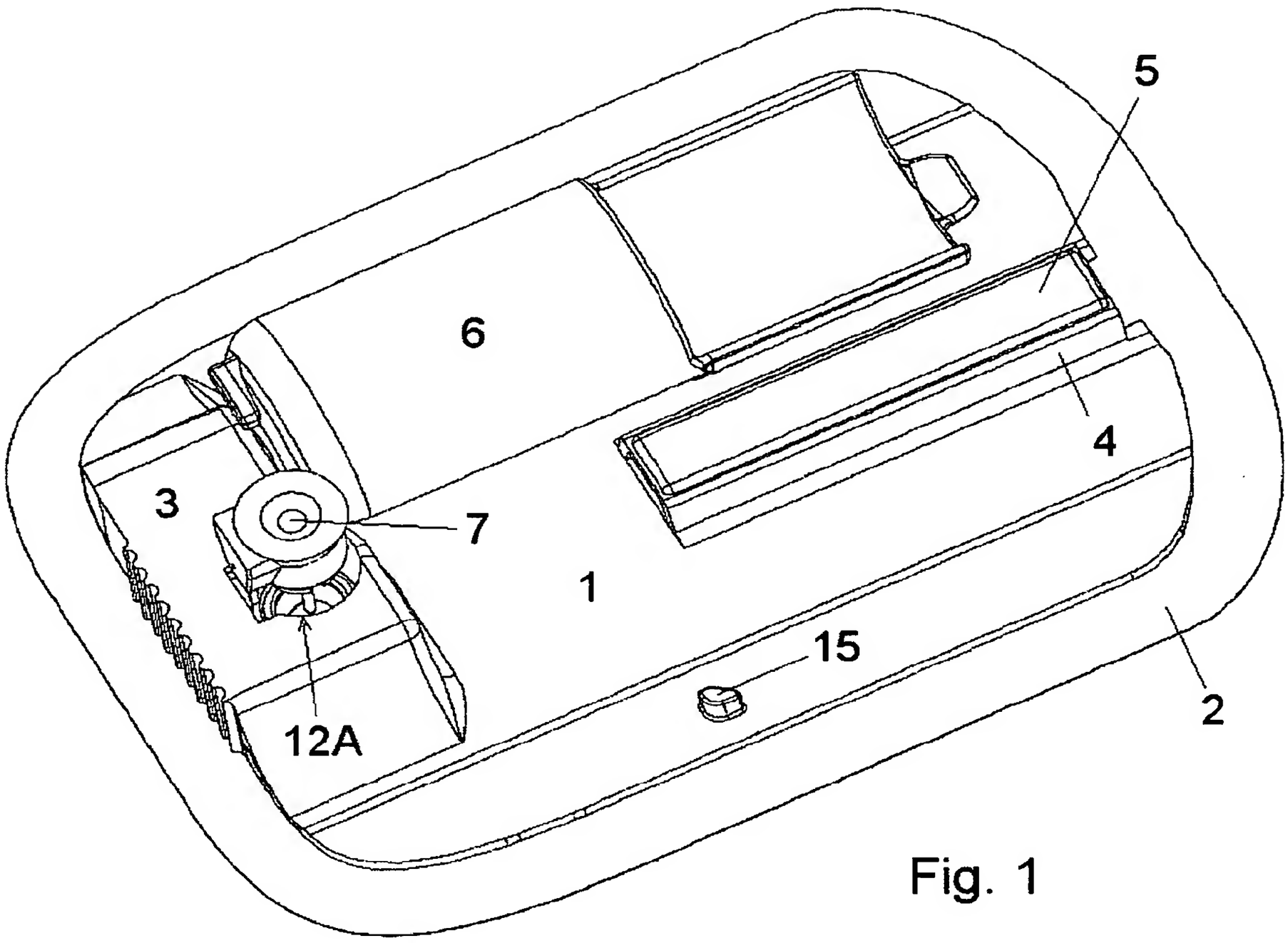


Fig. 1

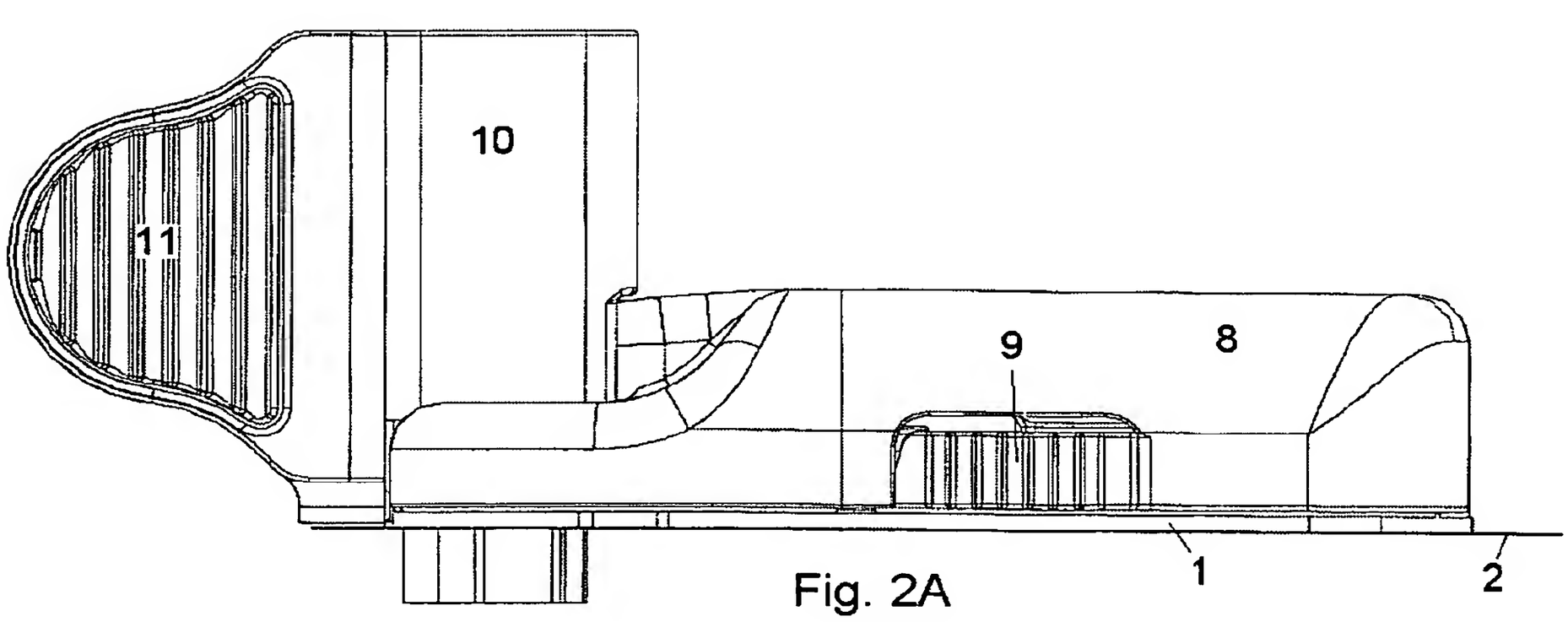


Fig. 2A

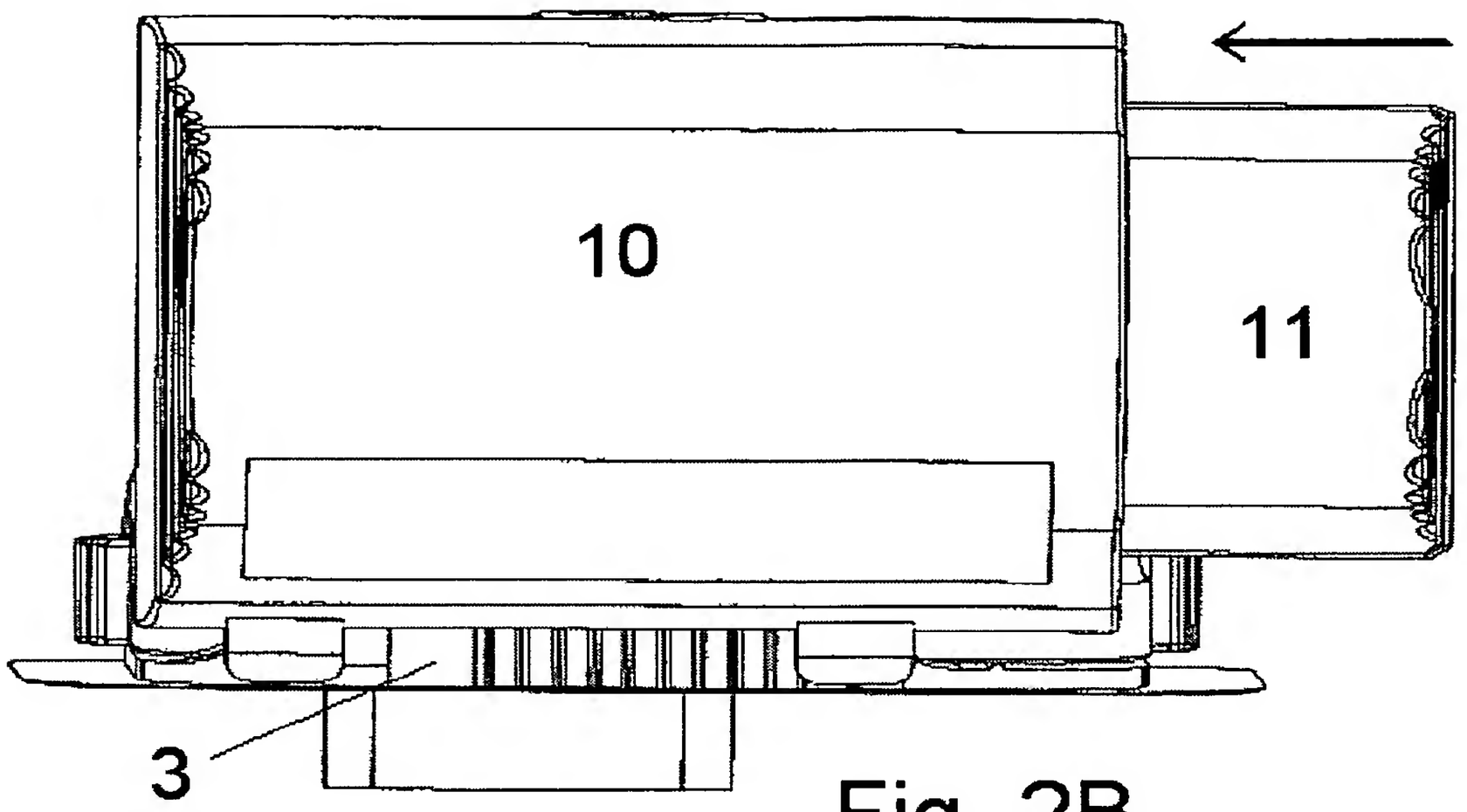


Fig. 2B

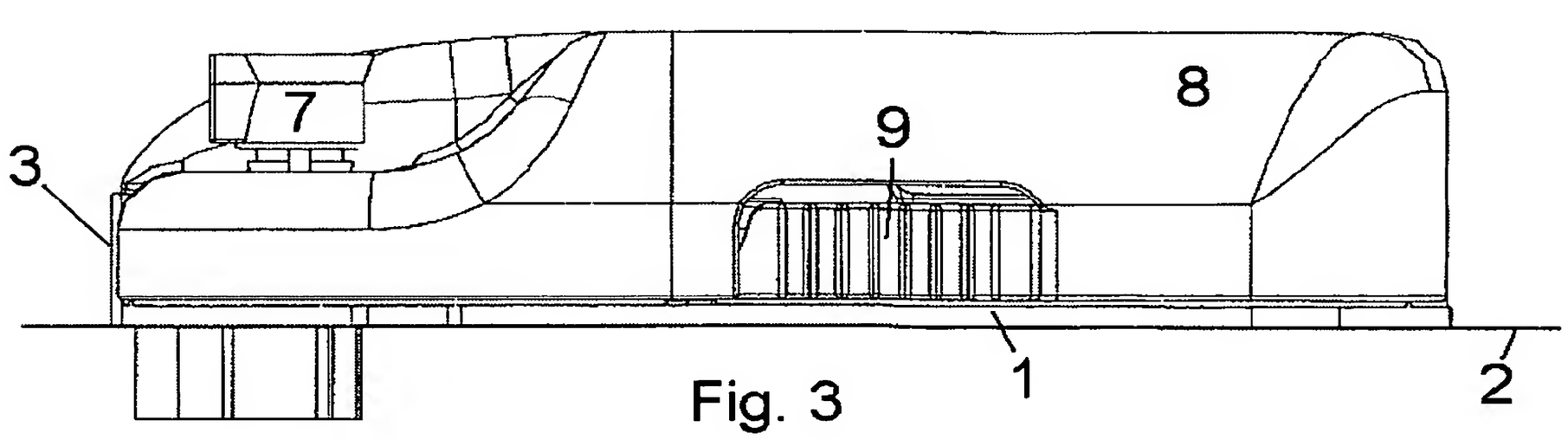


Fig. 3

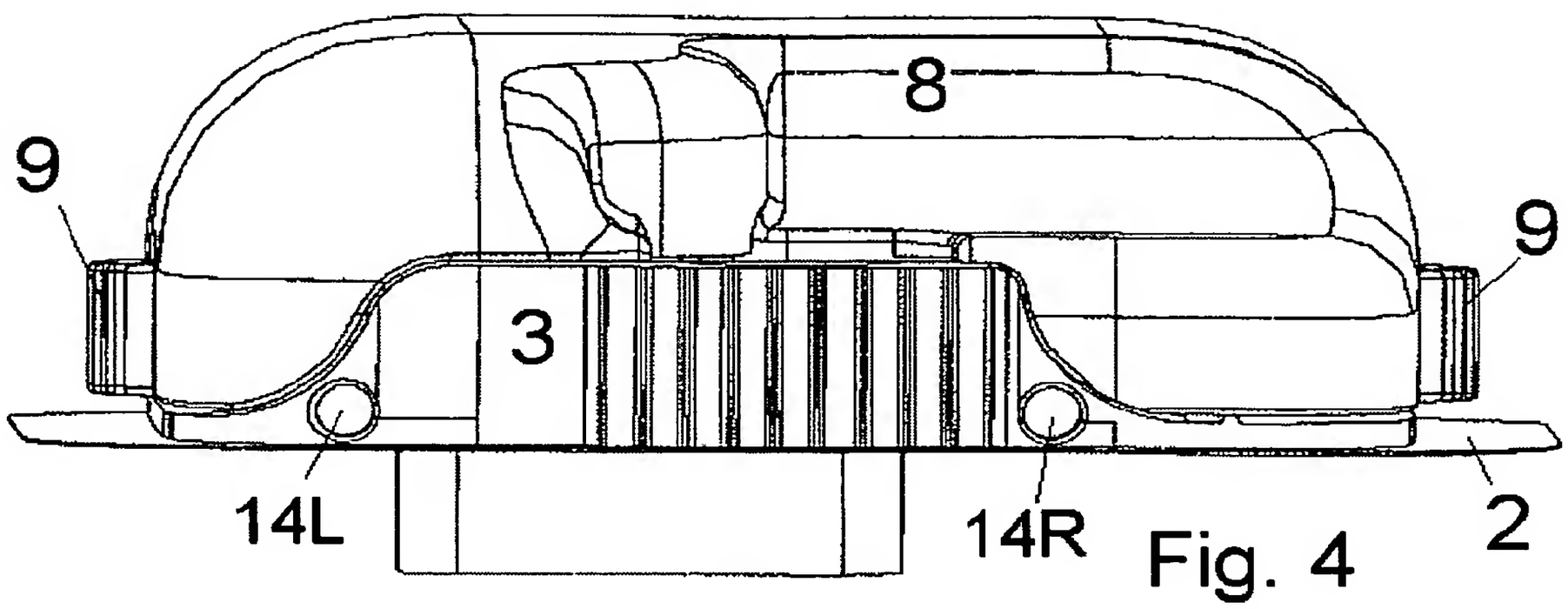


Fig. 4

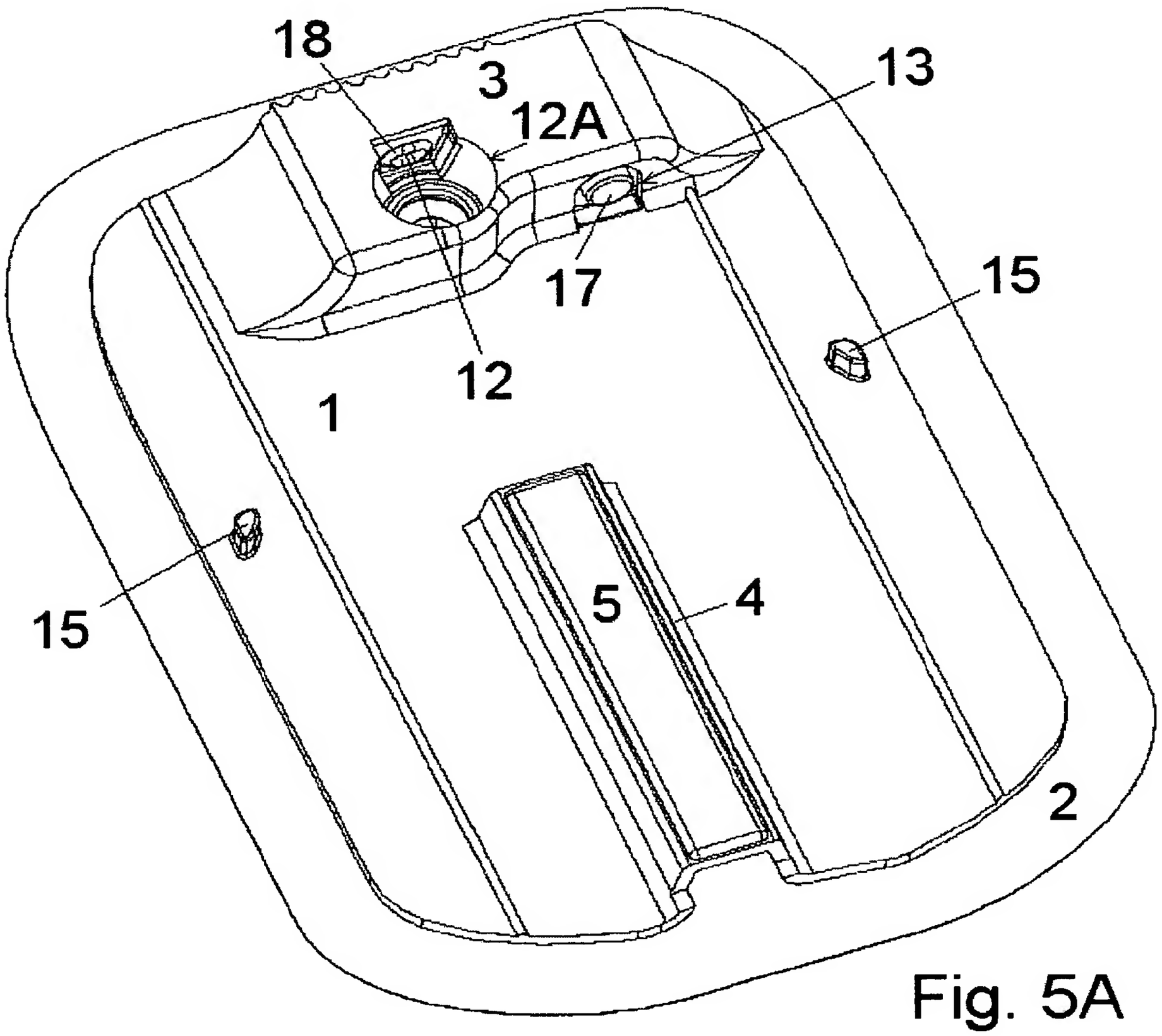


Fig. 5A

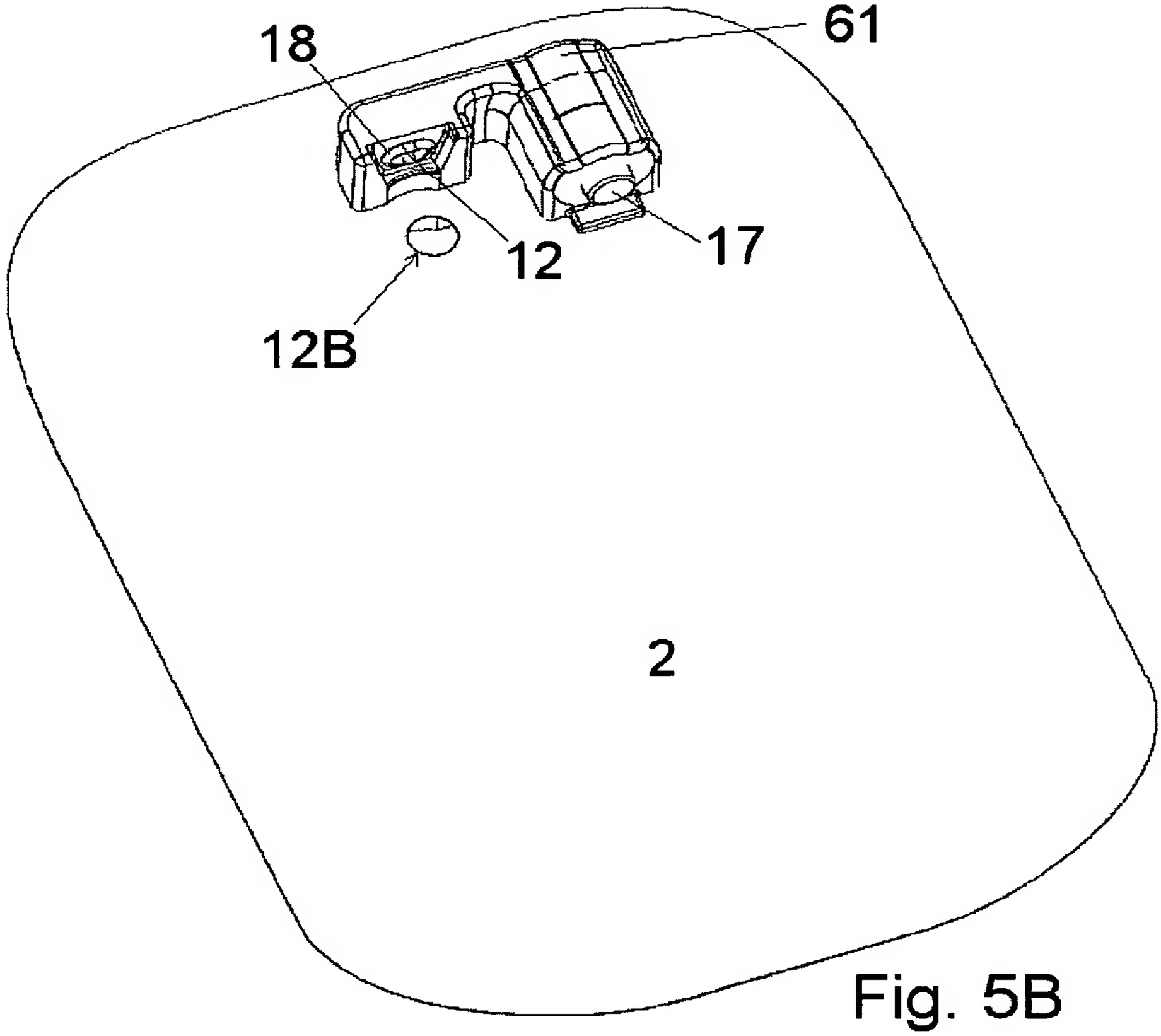


Fig. 5B

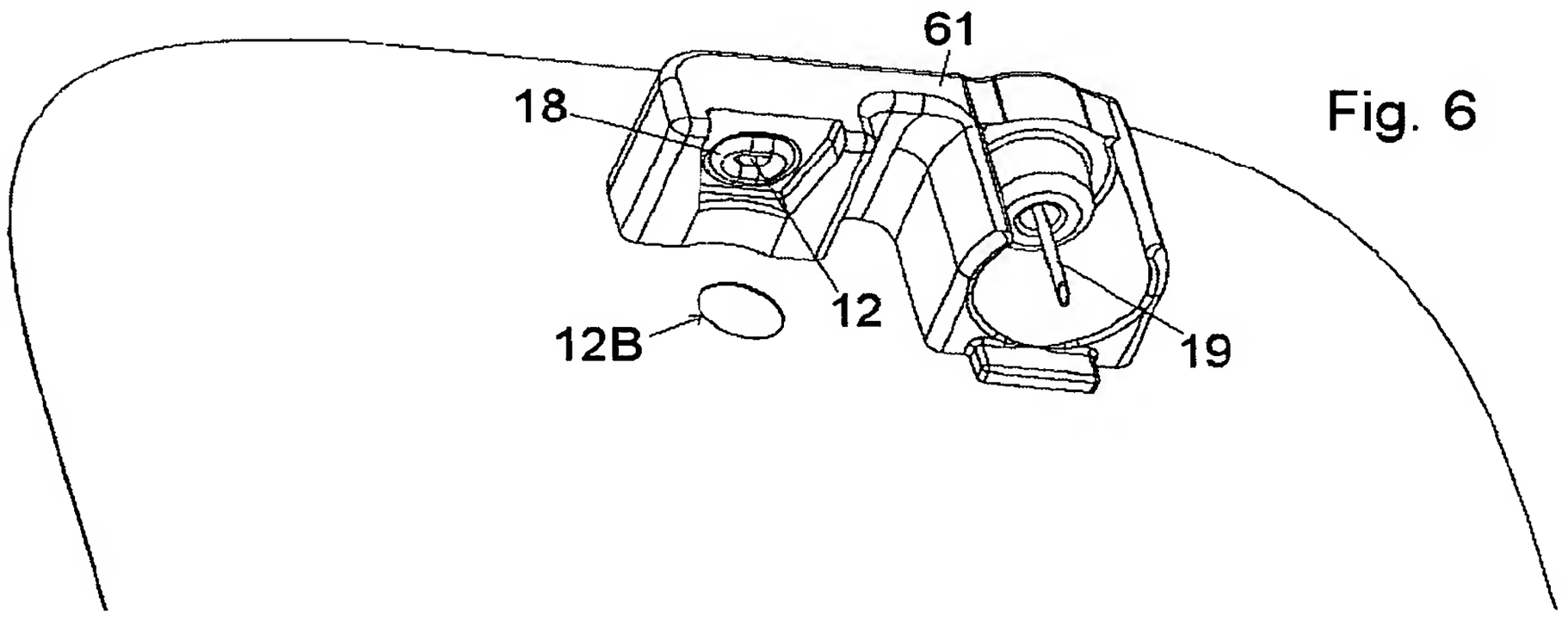


Fig. 6

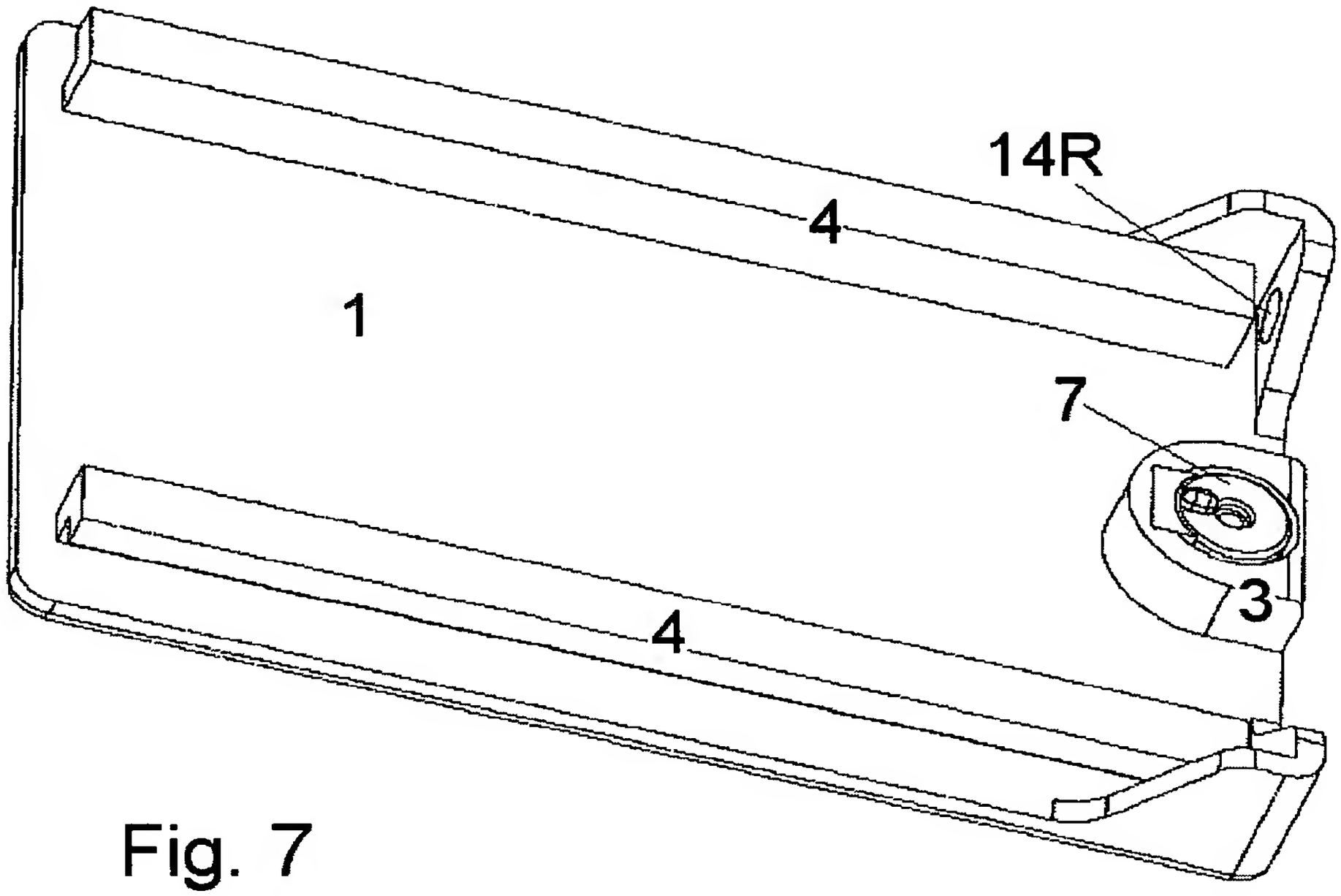


Fig. 7

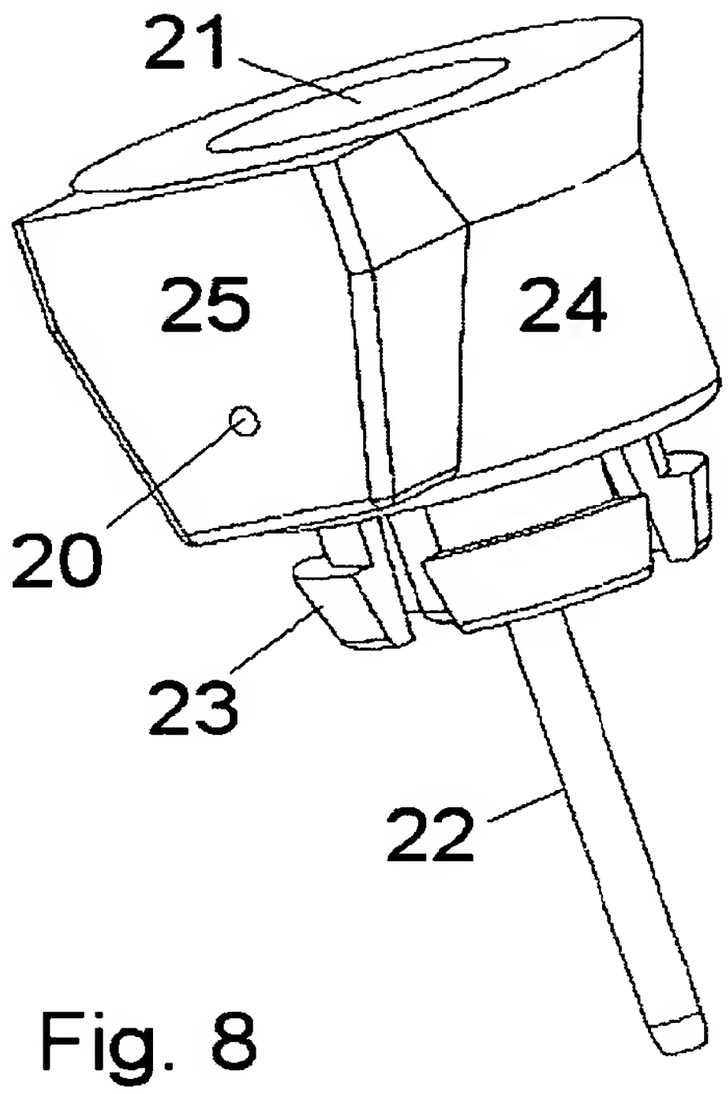


Fig. 8

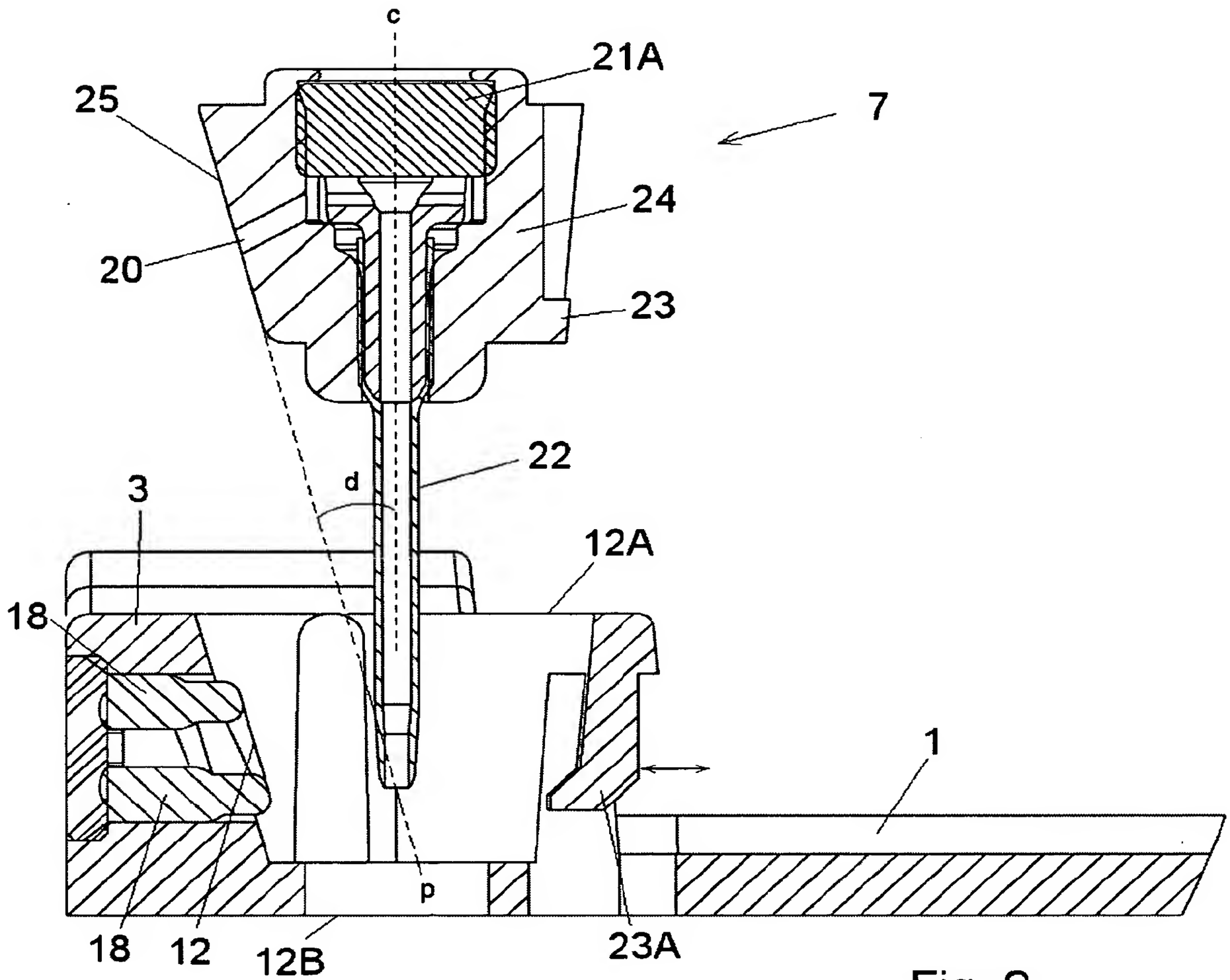


Fig. 9

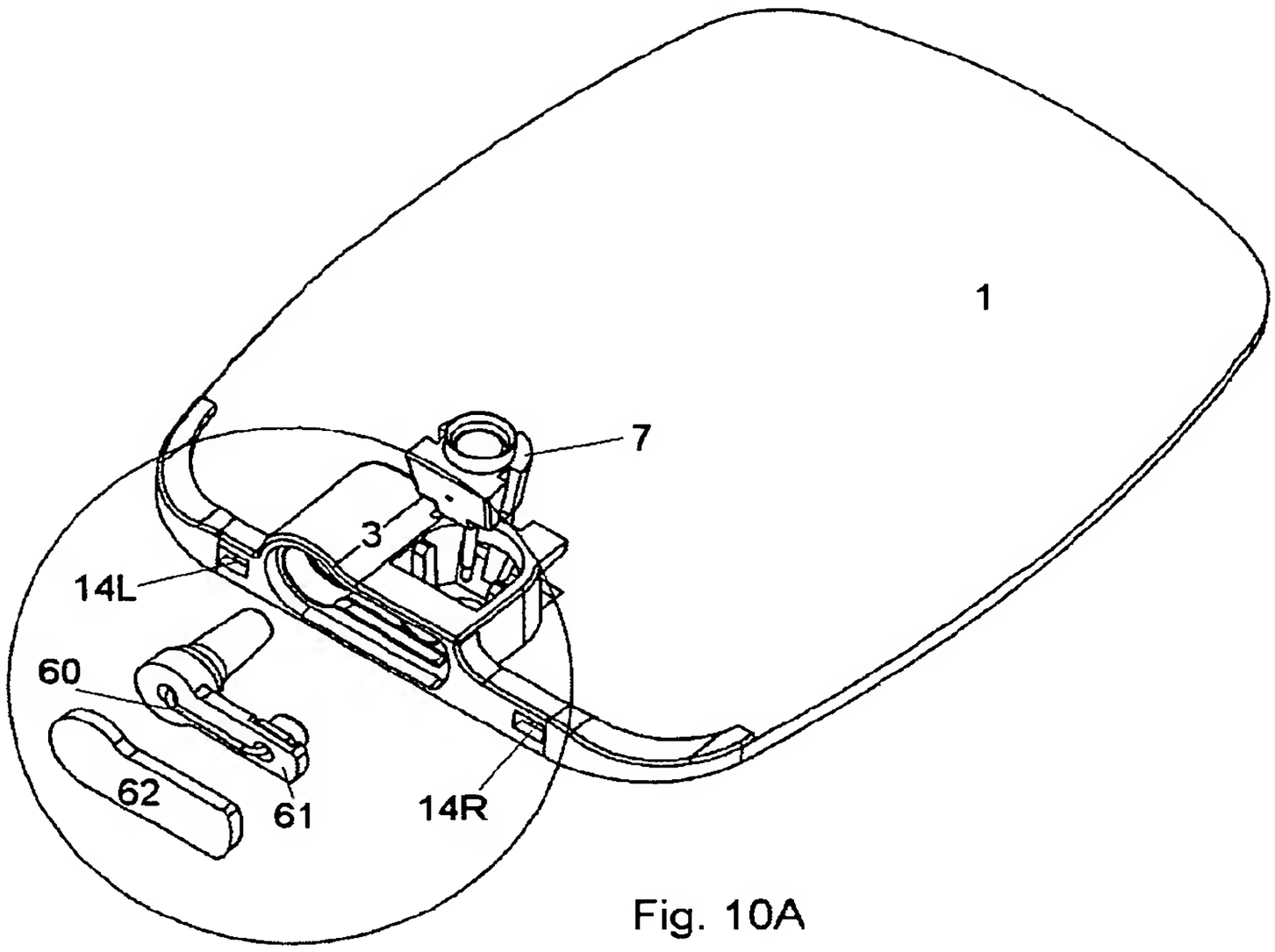


Fig. 10A

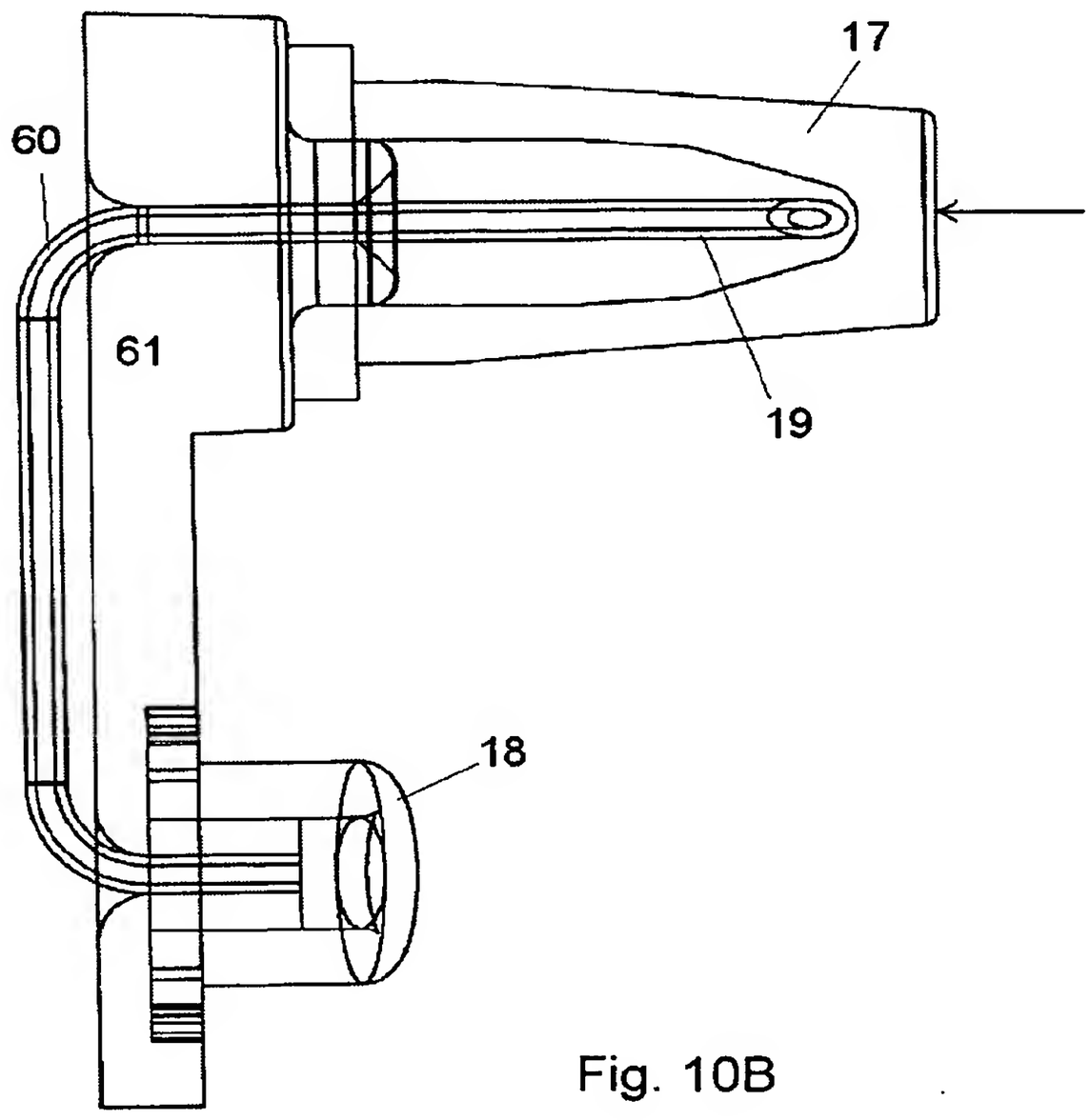


Fig. 10B

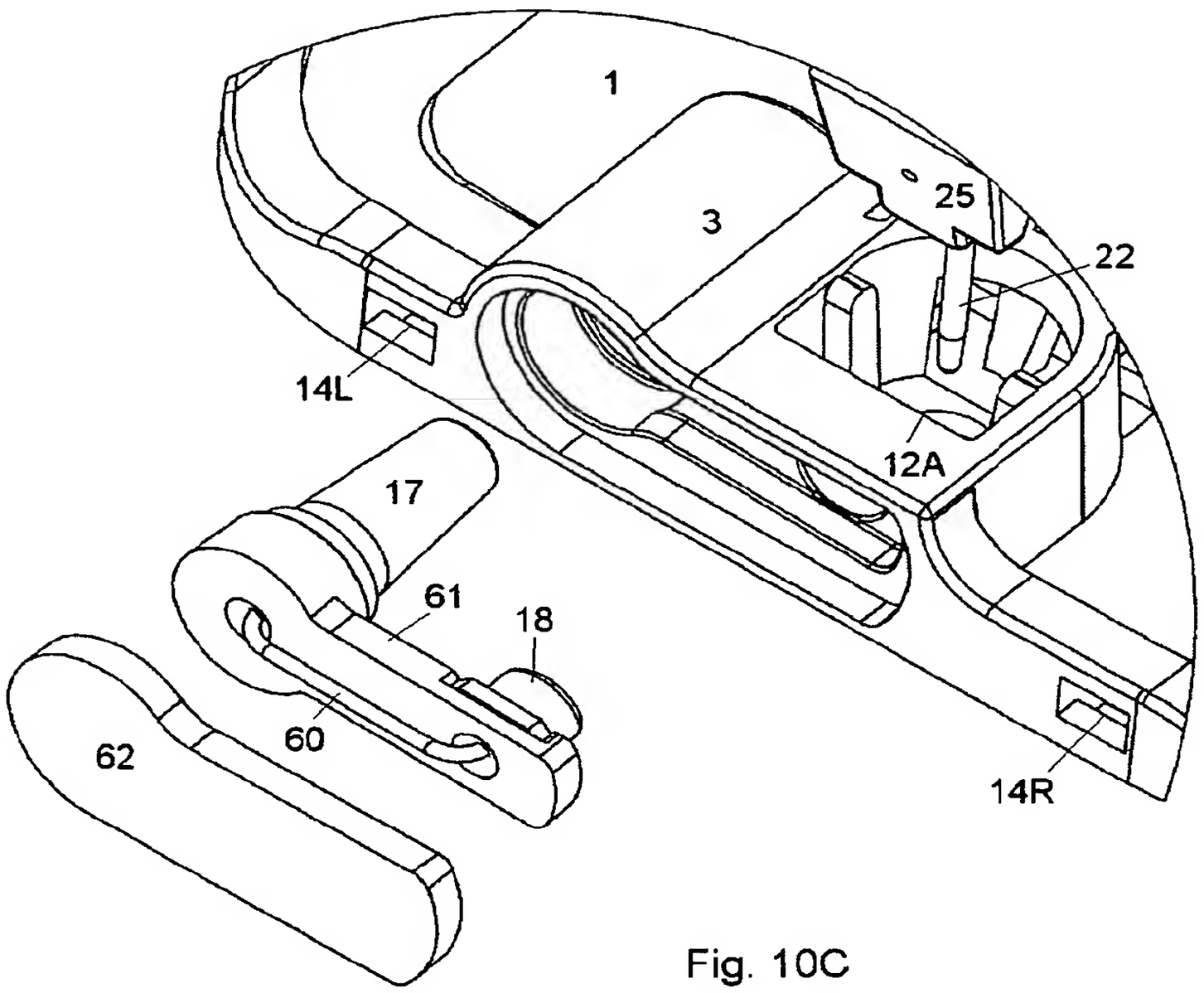


Fig. 10C

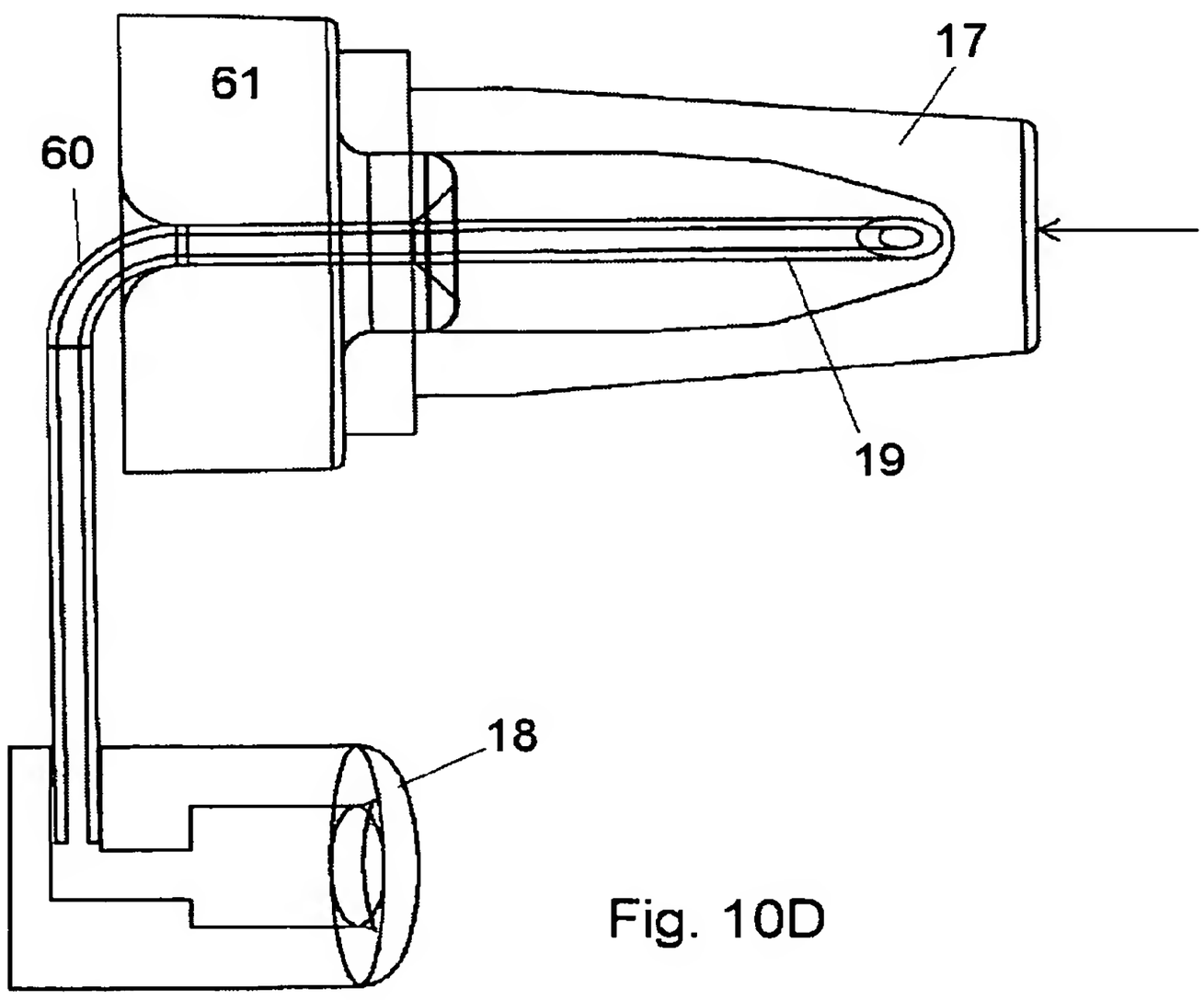


Fig. 10D

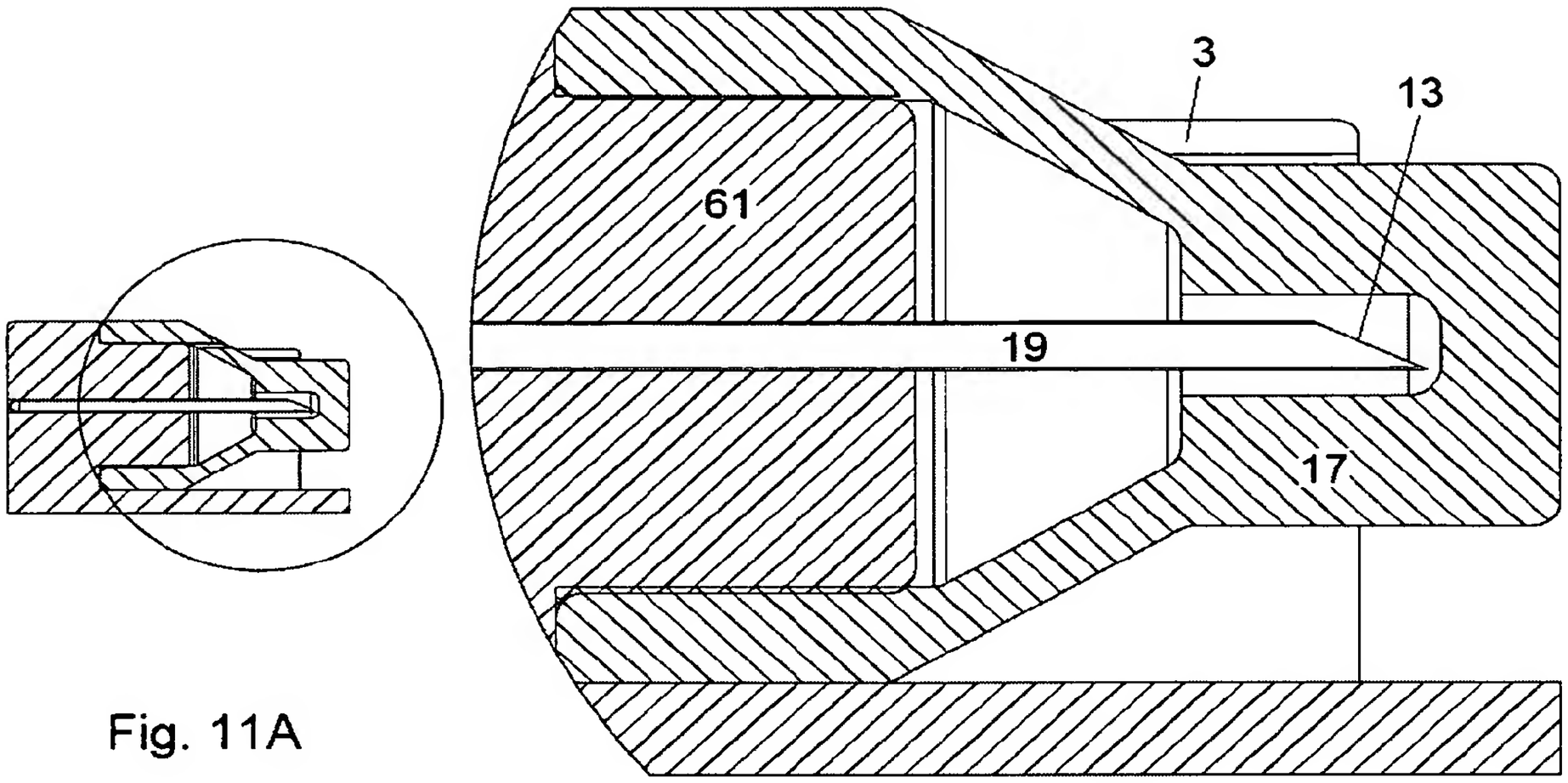


Fig. 11A

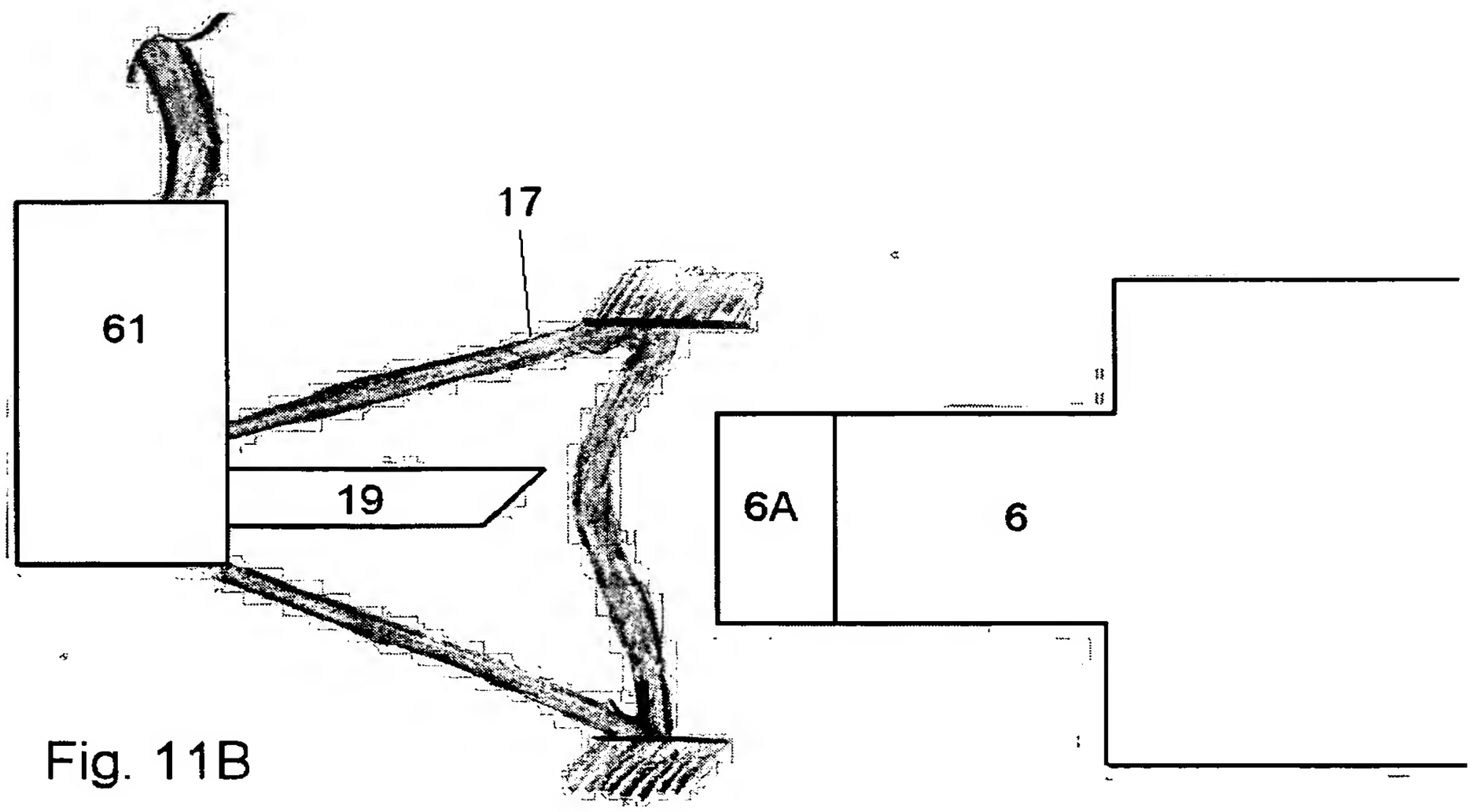


Fig. 11B

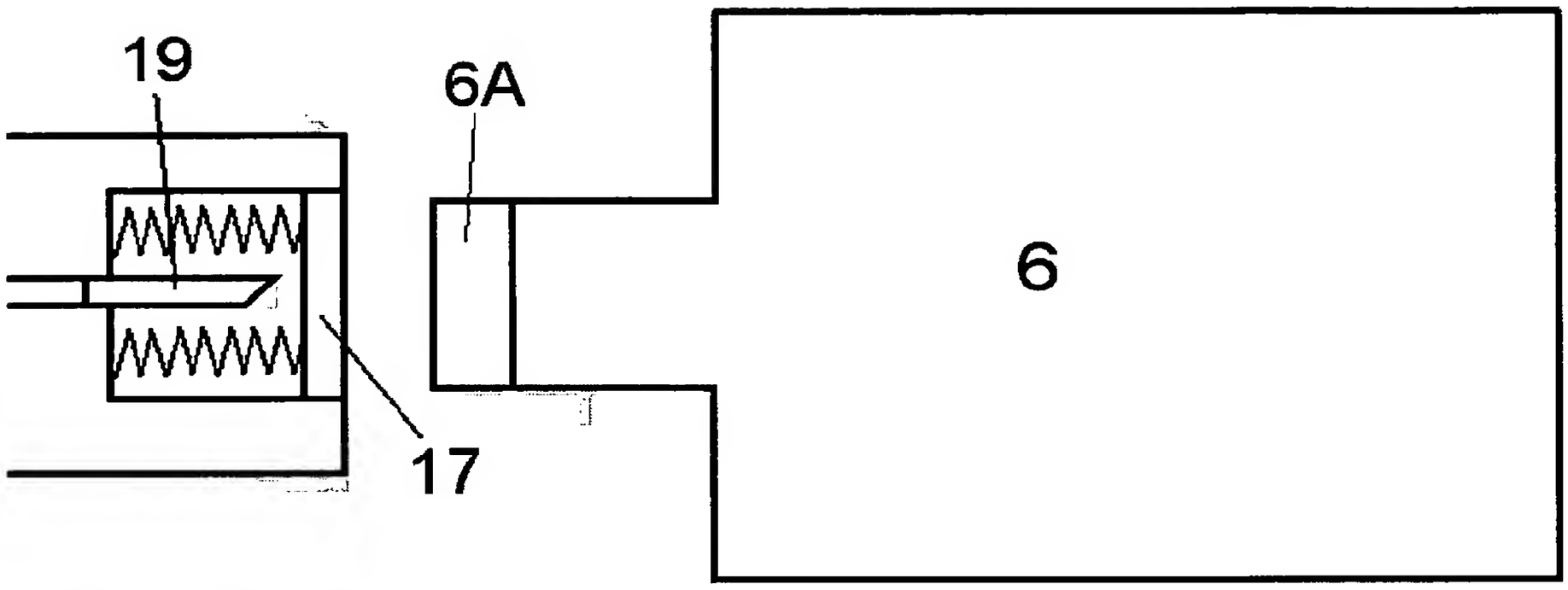


Fig. 11C

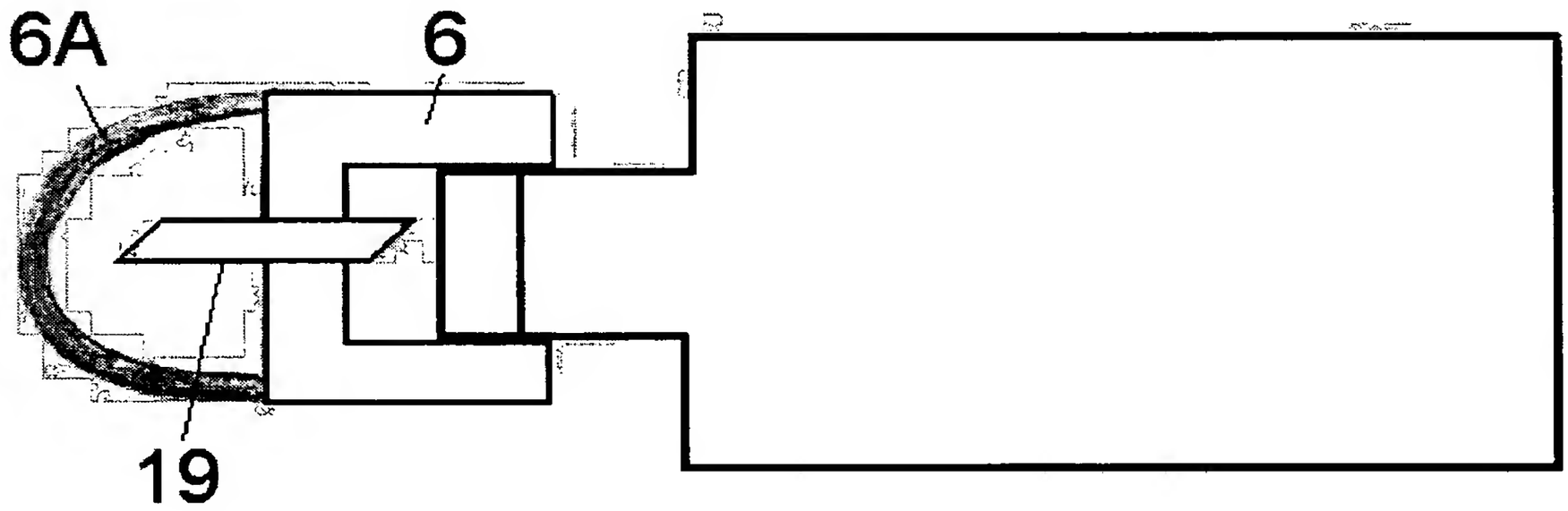


Fig. 11D

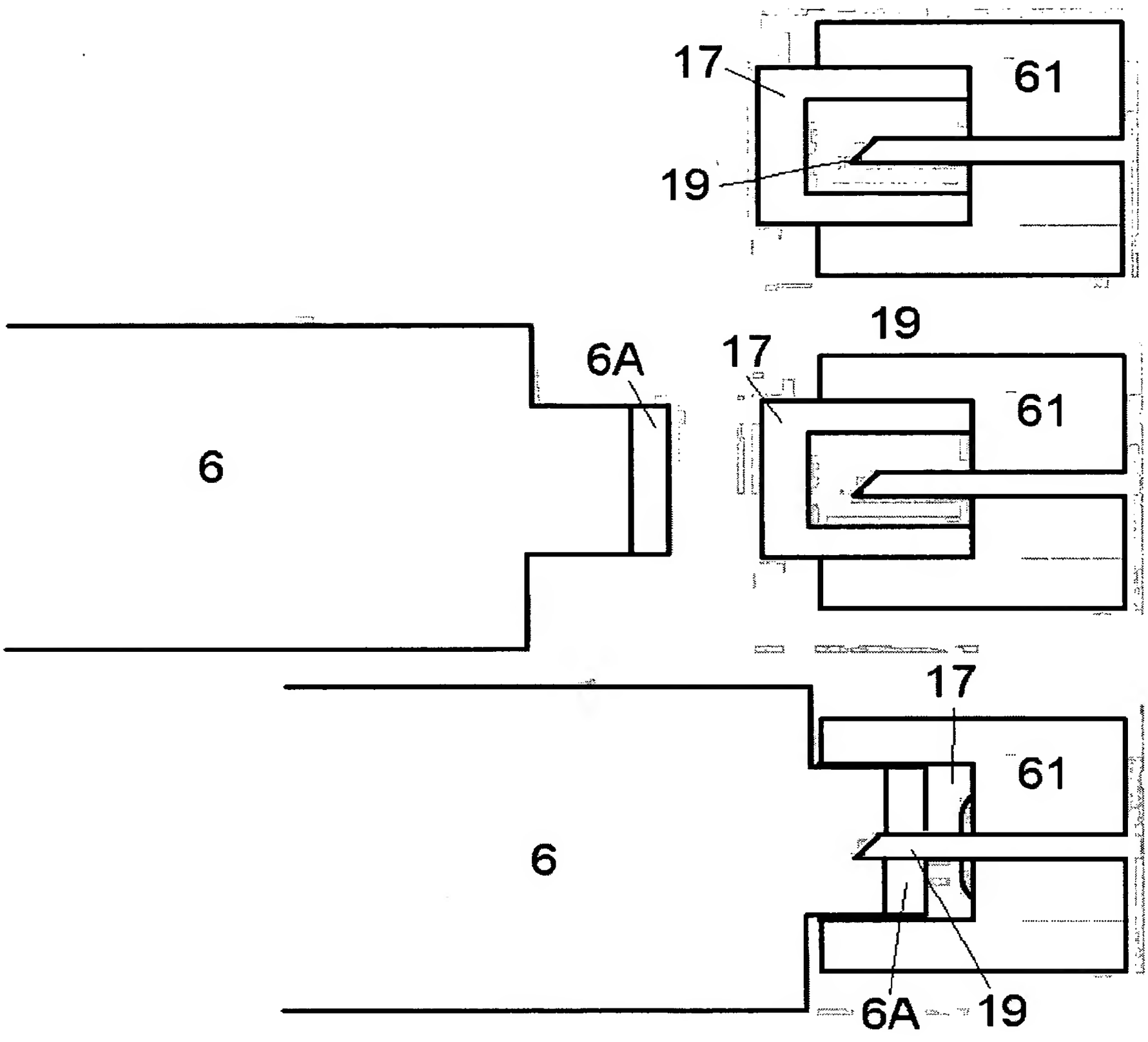


Fig. 11E

Fig. 12A

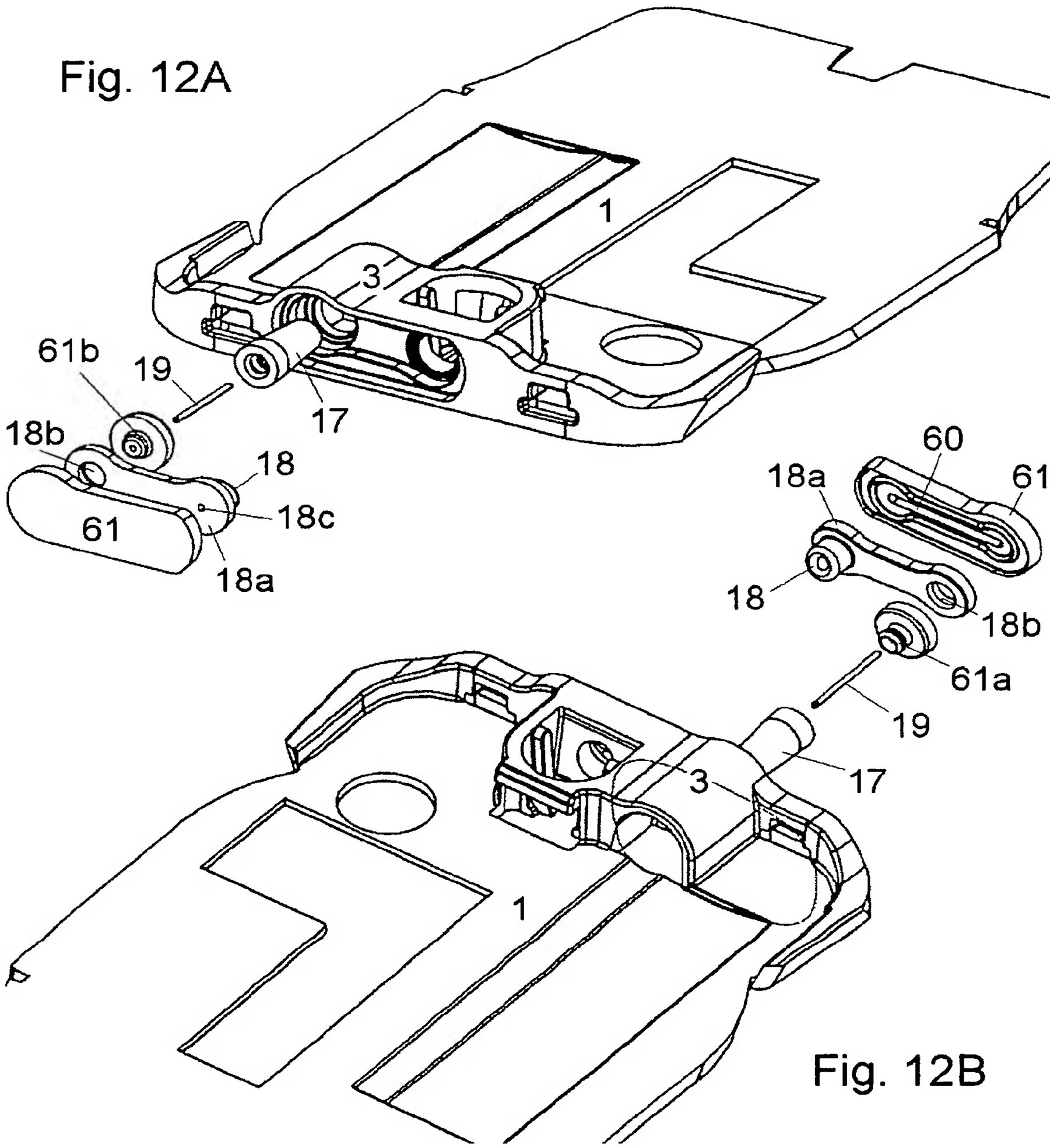
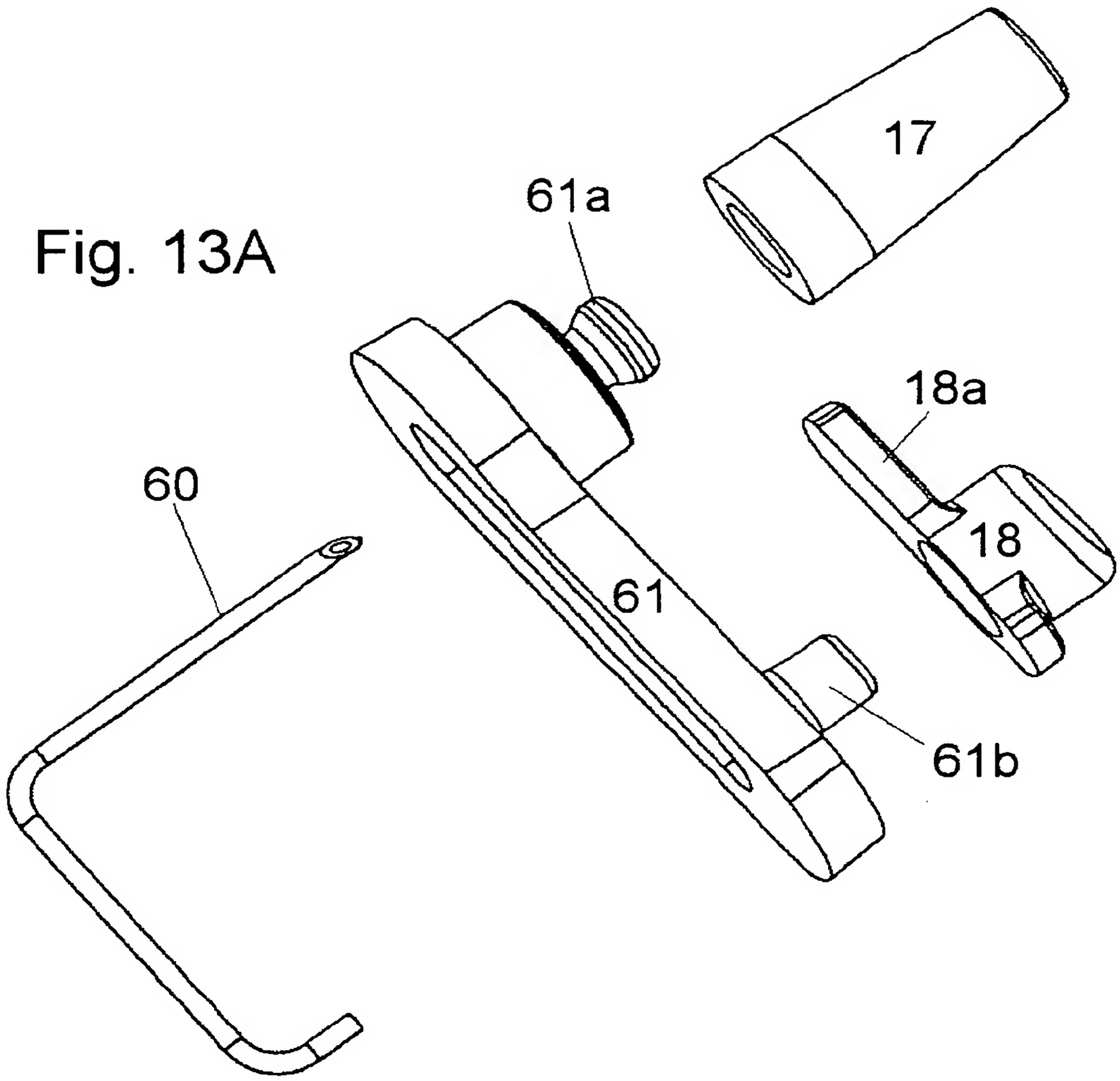


Fig. 12B

Fig. 13A



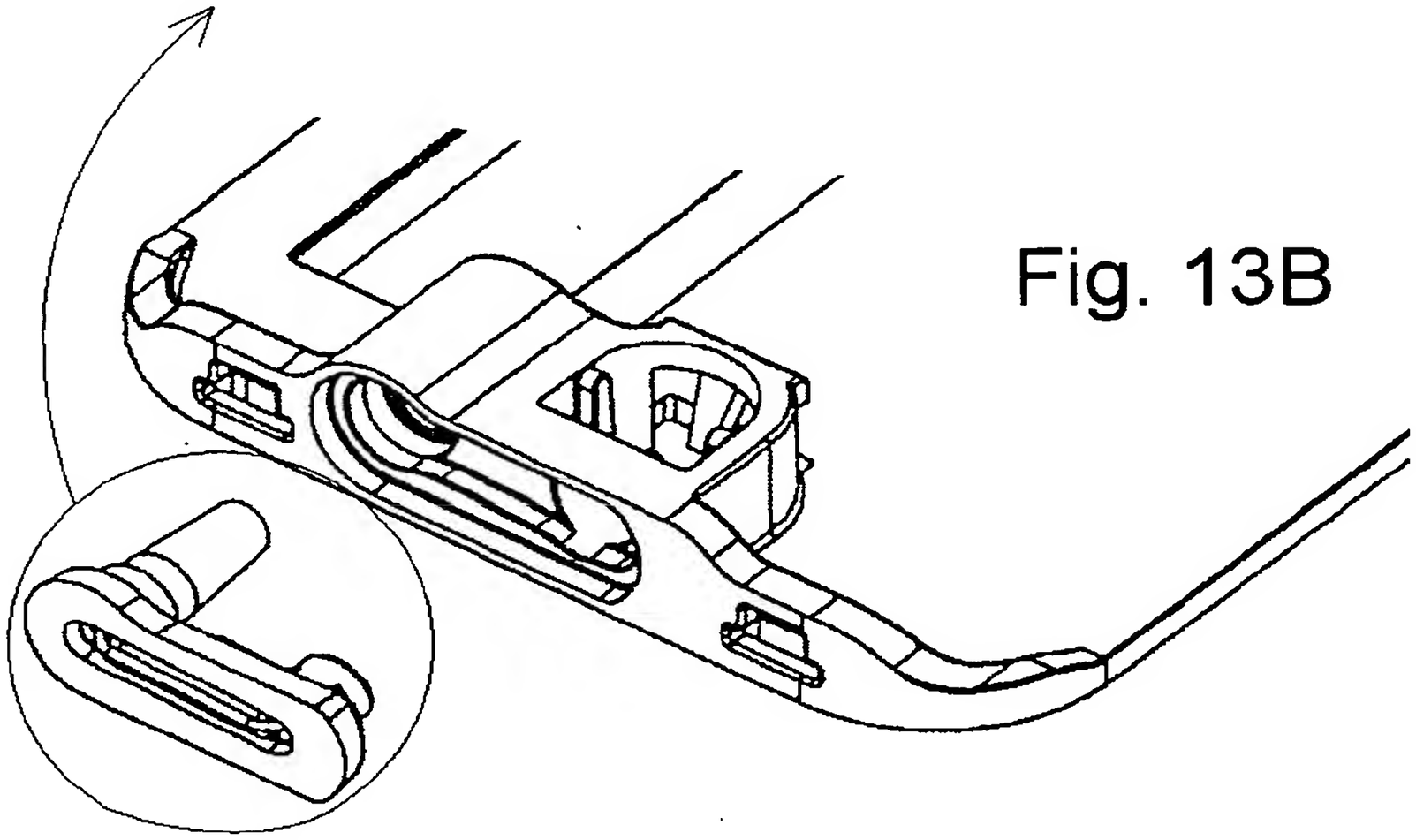


Fig. 13B

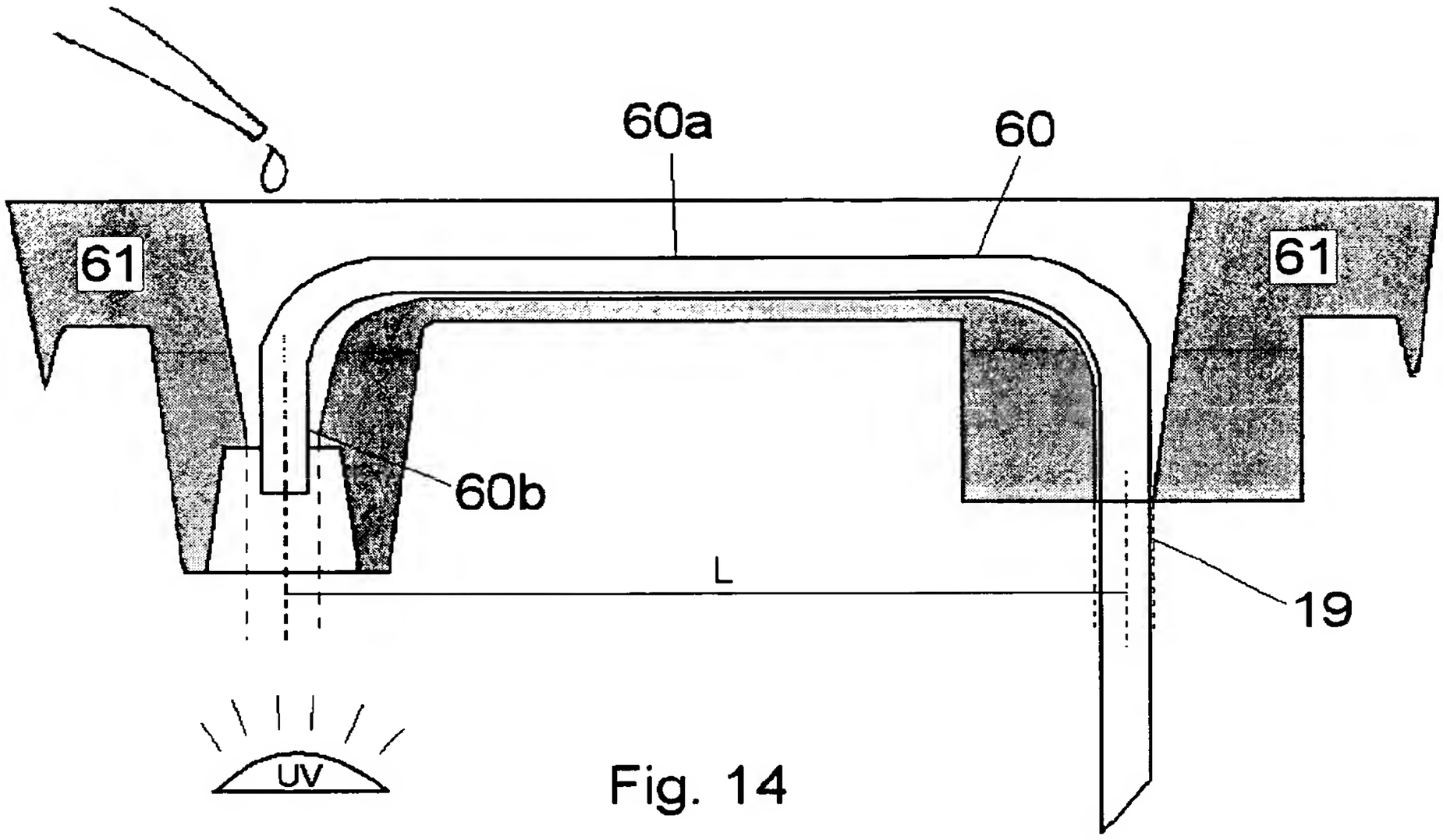


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/051653

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/158 A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/071255 A1 (UNOMEDICAL AS [DK]; MEJLHEDE SIGNE THORNING [DK]; MOGENSEN LASSE WESSE) 28 June 2007 (2007-06-28) the whole document	1-26
X	US 6 645 181 B1 (LAVI GILAD [IL] ET AL) 11 November 2003 (2003-11-11) the whole document	1
X	WO 2005/002649 A1 (NOVO NORDISK AS [DK]; RADMER JIM [DK]; KLINT HENRIK SOENDERSKOV [DK]) 13 January 2005 (2005-01-13) the whole document	1

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 June 2009	26/06/2009
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Authorized officer Ceccarelli, David

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/051653

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007071255 A1	28-06-2007	AT 429260 T	15-05-2009
		AU 2006329072 A1	28-06-2007
		CA 2634335 A1	28-06-2007
		CN 101365504 A	11-02-2009
		EP 1962925 A1	03-09-2008
		KR 20080089381 A	06-10-2008
		US 2009076453 A1	19-03-2009
US 6645181 B1	11-11-2003	US 2004015134 A1	22-01-2004
WO 2005002649 A1	13-01-2005	EP 1495775 A1	12-01-2005
		US 2006200073 A1	07-09-2006